MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING COMMENTS 1ST 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Section 9792.20(a)	Commenter states that the term "American College of Occupational and Environmental Medicine" does not need to be defined. Commenter requests that the definition be omitted from the proposed regulations. Commenter further states that if DWC must define the term, then he suggests that the definition describe ACOEM's composition or its mission.	Lachlan Taylor Commission on Health and Safety and Workers' Compensation December 22, 2006 Written Comment	**Disagree.** The comment does not address the proposed changes made to the regulations subject to the 15-day notice.	None.
Section 9792.20 [formerly subdivisions (a) and (d)]	Commenter opposes the deletion of the definitions of the terms "acute" and "chronic." Commenter agrees with DWC "that the distinction between an acute stage and a chronic stage of a condition is a clinical one," and reiterates his support for the adoption of the ACOEM guidelines. However, commenter disagrees that the application of ACOEM guidelines is appropriate for both acute and chronic conditions. Commenter opines that the ACOEM guidelines were specifically designed to provide guidance in the treatment of occupational injuries. Commenter states that while the guidelines are a useful tool for acute care management, the complexity of chronic conditions warrants greater clinical acumen and experience than that provided by ACOEM. Therefore, commenter opines that the definition of "acute" and "chronic" should not be deleted as proposed.	Joseph L. Dunn CEO/Executive Vice President California Medical Association December 22, 2006 Written Comment	**Disagree.** The comment is not specifically directed at the definitions of the terms "acute" and "chronic" but at the application of the ACOEM Practice Guidelines to chronic conditions. This comment was raised during the 45-day comment period and addressed in the original responses issued after 45-day comment period. The response to this comment is contained in Response No. 11—Chronic Conditions, which is part of the 45-day comment period chart.	None.
Section 9792.20 [formerly subdivisions (a) and (d)]	Commenter states that DWC attempts to address the issue of inappropriate application of the ACOEM Guidelines to chronic conditions by eliminating the definitions of "acute" and "chronic." Commenter disagrees with the revised regulations granting a presumption of correctness to the Medical Treatment Utilization Schedule (whether	Steven J. Cattolica Carlyle Brakensiek Advocal December 22, 2006 Written Comment	**Disagree.** The comment is not specifically directed at the definitions of the terms "acute" and "chronic" but at the application of the ACOEM Practice Guidelines to chronic conditions. This comment was raised during the 45-day comment period and addressed in the original	None.

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	ACOEM Guidelines, acupuncture guidelines or others to be added later) for the "duration of the condition." Commenter opines that as a consequence of this revision, alternate guidelines with similar published cautions will not be able to overcome the presumption awarded to guidelines currently within the schedule that carry the same admonition. Commenter opines that there will be no basis for considering requests for many, more appropriate, alternative treatments. This in turn, commenter predicts, will result in delays and costs.		responses issued after the 45-day comment period. The response to this comment is contained in Response No. 11—Chronic Conditions, which is part of the 45-day comment period chart. **Disagree.** Labor Code section 4604.5 provides that the adopted MTUS shall be presumptively correct on the issue of extent and scope of medical treatment, and that the presumption is rebuttable and may be controverted by a preponderance of the scientific medical evidence establishing that a variance from the guidelines is reasonably required to cure or relieve the injured worker from the effects of his or her injury. Section 9792.22(a) of the proposed regulations provides that the MTUS is presumptively correct on the issue of extent and scope of medical treatment and diagnostic services addressed in the MTUS for the duration of the medical condition. It further provides that the presumption is rebuttable and may be controverted by a preponderance of scientific medical evidence establishing that a variance from the schedule is reasonably required to cure or relieve the injured worker from the effects of his or her injury. If a physician recommends treatment	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING COMMENTS 1ST 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			that is at variance with the MTUS, a physician may provide scientific medical evidence which establishes that a variance from the schedule is reasonably required to cure or relieve the injured worker from the effects of the industrial injury. The statement in Section 9792.22(a) which states that the MTUS is presumptively correct for the duration of the medical condition does not change the burden of proof in overcoming the presumption.	
Section 9792.20 [formerly subdivisions (a) and (d)]	Commenter opposes the DWC's proposal to eliminate the definition of the terms "acute" and "chronic." Commenter opines that the DWC has an opportunity to provide clarity on this issue which has been a significant point of contention in the past. Commenter further opines that without a definition of these terms in the regulations, injured workers may not get the most appropriate care for their injuries and litigation will be encouraged.	John Bueler, Jr., DC President California Chiropractic Association December 22, 2006 Written Comment	**Disagree.** It appears that the comment is not specifically directed at the definitions of the terms "acute" and "chronic" but at the application of the ACOEM Practice Guidelines to chronic conditions. This comment was raised during the 45-day comment period and addressed in the original responses issued after the 45-day comment period. The response to this comment is contained in Response No. 11—Chronic Conditions, which is part of the 45-day comment period chart. Specifically, Response No. 11—Chronic Conditions, states that DWC agrees that the distinction between an acute stage and a chronic stage of a condition is a clinical one. DWC believes that because the intent of the regulations is to state that the MTUS applies to all conditions for the duration of the medical condition, the definitions of the terms "acute"	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING COMMENTS 1ST 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			(Section 9792.20(a)), and "chronic" (Section 9792.20(d)) are not necessary. Moreover, DWC believes that to the contrary, litigation will be discouraged because it will be up to the treating physician to continue to provide medical care to the injured worker pursuant to the MTUS as opposed to having the parties litigate whether the stage of the condition is acute or chronic thus preventing the injured worker from receiving treatment while the litigation is pending.	
Section 9792.20 [formerly subdivisions (a) and (d)]; Section 9792.22(a)	Commenter opines that ACOEM itself is limited to the treatment of acute conditions. Commenter further opines that while it may be the case that the proposed regulations cannot force what may well be a clinical distinction, in his opinion, the ACOEM guidelines make the distinction between acute and chronic and then clearly do not apply to chronic conditions. Commenter further states that this same issue was addressed in *Hamilton v. SCIF* (32 CWCR 249, Board Panel Decision), wherein the workers' compensation judge held that the ACOEM guidelines were inapplicable by their very definition.	Bo Thoreen, Esq. December 22, 2006 Written Comment	**Disagree.** The comment is not specifically directed at the definitions of the terms "acute" and "chronic" but at the application of the ACOEM Practice Guidelines to chronic conditions. This comment was raised during the 45-day comment period and addressed in the original responses issued after 45-day comment period. The response to this comment is contained in Response No. 11—Chronic Conditions, which is part of the 45-day comment period chart. Moreover, Response No. 11—Chronic Conditions, also addressed the *Hamilton v. Goodwill Industries* case, at page 7.	None.
Section 9792.20 [formerly subdivisions (a) and (d)]; Section 9792.22(a)	In reference to the deletion of the definitions of the terms "acute" and "chronic," commenter indicates that she is not sure what the subsequent amendment to proposed Section 9792.22(a), stating that the Medical	Linda F. Atcherley President California Applicants' Attorneys Association December 22, 2006	**Disagree.** The comment is not specifically directed at the definitions of the terms "acute" and "chronic" but at the application of the ACOEM Practice Guidelines to chronic	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING COMMENTS 1ST 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	Treatment Utilization Schedule is presumptively correct "for the duration of the medical condition" means. Accordingly, commenter repeats her previous comments that it is improper and potentially harmful to injured workers to designate any treatment or diagnostic services as presumptively correct where there is no evidence demonstrating that this treatment or service is appropriate. Commenter states that if a treatment or service guideline in ACOEM, or any other published guidelines is identified as appropriate only for a specified period or phase of an injury or illness, that treatment or service should not be designated as presumptively correct outside of that period or phase.	Written Comment	conditions. This comment was raised during the 45-day comment period and addressed in the original responses issued after 45-day comment period. The response to this comment is contained in Response No. 11—Chronic Conditions, which is part of the 45-day comment period chart. Moreover, "the duration of the medical condition" means as long as the injured worker is receiving treatment that would fall under the proposed regulations. Labor Code section 4604.5 provides that the adopted MTUS shall be presumptively correct on the issue of extent and scope of medical treatment, and that the presumption is rebuttable and may be controverted by a preponderance of the scientific medical evidence establishing that a variance from the guidelines is reasonably required to cure or relieve the injured worker from the effects of his or her injury. Section 9792.22(a) of the proposed regulations provides that the MTUS is presumptively correct on the issue of extent and scope of medical treatment and diagnostic services addressed in the MTUS for the duration of the medical condition. It further provides that the presumption is rebuttable and may be controverted by a preponderance of scientific	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING COMMENTS 1ST 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			medical evidence establishing that a variance from the schedule is reasonably required to cure or relieve the injured worker from the effects of his or her injury. If a physician recommends treatment that is at variance with the MTUS, a physician may provide scientific medical evidence which establishes that a variance from the schedule is reasonably required to cure or relieve the injured worker from the effects of the industrial injury. The statement in Section 9792.22(a) which states that the MTUS is presumptively correct for the duration of the medical condition does not change the burden of proof in overcoming the presumption. **Disagree** with comment that the MTUS is not evidence-based. In the article *Evidence Based Medicine: What it is and What it isn't*, http://www.bmj.com/cgi/content/full/312/7023/71, the concept of evidence-based medicine is discussed as follows: "[e]vidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING COMMENTS 1ST 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			evidence from systematic research." Moreover, in discussing the definition of evidence-based medicine, *Crossing the Quality Chasm*, at p. 147, states "[c]ontemporary definitions also clarify that 'evidence' is intended to refer not only to randomized controlled trials, the 'gold standard,' but also to other types of systematic acquired information." Thus, the comment that "it is improper and potentially harmful to injured workers to designate any treatment or diagnostic services as presumptively correct where there is no evidence demonstrating that this treatment or service is appropriate" is incorrect because the concept of evidence-based medicine is based on finding the best evidence to support medical recommendations.	
Section 9792.20(b)	Commenter believes the language should be revised to read as follows: "(b)ACOEM Practice Guidelines" means the American College of Occupational and Environmental Medicine's Occupational Medicine Practice Guidelines, 2nd Edition (2004), published by the American College of Occupational and Environmental Medicine. The Administrative Director incorporates the ACOEM Practice Guidelines by reference. A copy may be obtained from American College of Occupational and Environmental Medicine, 25 Northwest Point Blvd., Suite 700, Elk Grove Village, Illinois, 60007-1030	Pat O'Connor Director of Government Affairs – ACOEM December 22, 2006 Written Comment	**Agree**. Section 9792.20 (b) should be amended to the proposed regulations to reflect the source where a copy of the ACOEM Practice Guidelines, 2nd Edition, may be obtained. Section 9792.20 (b) will be amended to reflect that a copy of the ACOEM Practice Guidelines, 2nd Edition may be obtained from American College of Occupational and Environmental Medicine, 25 Northwest Point Blvd., Suite 700, Elk Grove Village, Illinois, 60007-1030 (www.acoem.org)."	Section 9792.20(b) has been amended to reflect that a copy of the ACOEM Practice Guidelines, 2nd Edition, may be obtained from American College of Occupational and Environmental Medicine, 25 Northwest Point Blvd., Suite 700, Elk Grove Village, Illinois, 60007-1030 (www.acoem.org)

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING COMMENTS 1ST 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	(www.acoem.org)."			
Section 9792.20(b)	Commenter cites Section 77(b) of Legislative Drafting Manual, an undated document of the Office of Legislative Counsel apparently prepared approximately in 1975, for his recommendation that there should not be incorporation by reference in the definition of the term "ACOEM Practice Guidelines." Commenter further objects to the definition of the term "ACOEM Practice Guidelines," proposing that the definition reflect that future updates of the ACOEM Practice Guidelines be automatically adopted and incorporated into the regulations.	Lachlan Taylor Commission on Health and Safety and Workers' Compensation December 22, 2006 Written Comment	**Disagree.** The comment does not address the proposed changes made to the regulations subject to the 15-day notice. **Disagree.** The comment does not address the proposed changes made to the regulations subject to the 15-day notice. This comment was raised during the 45-day comment period and addressed in the original responses issued after 45-day comment period. Response No. 1—Adoption by Incorporation by Reference an Existing Document and Any Future Updates, which is part of the 45-day comment period chart, thoroughly addresses this issue.	None. None.
Section 9792.20(b) and 9792.21(a)(1)	Commenter objects to the reference in Sections 9792.20(b) and 9792.21(a)(1) to the *American College of Occupational and Environmental Medicine's Occupational Medicine Practice Guidelines, Second Edition (2004)*. Commenter opines that the reference to the Second Edition would make it necessary to undertake a new rulemaking proceeding whenever the ACOEM Practice Guidelines are updated. Commenter believes that the references should be changed to the "most current version" of the ACOEM Practice Guidelines. Commenter opines that this change is consistent with the definition of "medical treatment guidelines" in Section	Samuel Sorich President Association of California Insurance Companies December 22, 2006 Written Comment	**Disagree.** The comment does not address the proposed changes made to the regulations subject to the 15-day notice. This comment was raised during the 45-day comment period and addressed in the original responses issued after the 45-day comment period. Response No. 1—Adoption by Incorporation by Reference an Existing Document and Any Future Updates, which is part of the 45-day comment period chart, thoroughly addresses this issue. With regard to the comment that the proposed regulations in the definition	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING COMMENTS 1ST 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	9792.20(g) which refers to the "most current version" of guidelines.		of the term "medical treatment guidelines" require that the guideline being used be the "most current version," it is noted that these guidelines are not incorporated into the proposed regulations thus there is no requirement for formal rulemaking, and Response No. 1 above is not applicable.	
Section 9792.20(e)	Commenter states that the definition offered for "functional improvement" seems valid and useful although perhaps too limiting to apply in all cases. Commenter opines that not all useful treatment results so immediately in "functional improvement." Commenter believes that the definition, if construed too tightly, could be used to deny appropriate continued treatment. Commenter suggests that the definition take in some additional criteria beyond "functional improvement," such as "other justification specific to the individual case." Commenter suggests that defining this "other justification" – what it is and how to measure it – could be part of the work of the new Advisory Committee.	Steven C. Schumann, MD Legislative Chair Western Occupational & Environmental Medical Association (WOEMA) December 22, 2006 Written Comment	**Disagree.** The definition of the term functional improvement will be applicable to specific treatments as set forth in the MTUS, such as use of acupuncture for musculoskeletal conditions. It is clear from the text of the regulations that this definition will not apply to conditions that do not result in a functional outcome, such as for example, the treatment of hypertension or the treatment of diabetes where the desired outcome is to control blood pressure and blood sugar.	None.
Section 9792.20(e)	Commenter recommends that a comma be placed following the phrase "physical exam" in the definition of the term "functional improvement." Commenter states that the comma is significant because it will clarify that not only the reduction in work restrictions, but also the clinically significant improvement in activities of daily living, are measured during the history and physical exam and must be documented as part of the evaluation and management visit billed under the Official Medical Fee Schedule (OMFS).	Brenda Ramirez Claims and Medical Director Michael McClain General Counsel & Vice President Alex Swedlow Executive Vice President California Workers'	**Agree.** The recommended comma following the phrase "physical exam" in the definition of the term "functional improvement" clarifies that not only the reduction in work restrictions, but also the clinically significant improvement in activities of daily living, are measured during the history and physical exam and must be documented as part of the evaluation and management visit billed under the Official Medical Fee	Section 9792.20(e) has been amended to insert a comma following the phrase "physical exam" in the definition of the term "functional improvement."

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		Compensation Institute December 22, 2006 Written Comment	Schedule (OMFS).	
Section 9792.20(e)	Commenter recommends that the word "significant" which precedes the word "improvement" in the proposed definition of the term "functional improvement" be stricken. Commenter opines that "significant" is a subjective term and sets too high of a standard. Commenter states that the goal should be for the patient to show clinical improvement. Commenter adds that when a doctor believes a patient is continuing to improve and needs further treatment, the patient should receive that treatment. Commenter further opines that the definition denies the clinical significance of a chronic condition that does not demonstrate improvement meeting this definition. Commenter believes that applying this proposed definition to chronic conditions will result in the denial of continued care if the measurement of improvement is not demonstrated. Commenter also states that as indicated by the DWC in its notice, the proposed definition of the term "functional improvement" is adapted from ACOEM's medical treatment philosophy. Commenter opines that the ACOEM practice guidelines presuppose that an injured worker will return successfully to work, and that this concept does not allow for the many patients who are unable to return to the workforce in any capacity. Commenter believes this is an example of why the ACOEM Practice Guidelines are inappropriate	Joseph L. Dunn CEO/Executive Vice President California Medical Association December 22, 2006 Written Comment	**Disagree.** Use of the word "significant" to modify the word "improvement" in the definition of the term "functional improvement" is appropriate. The modifying adjective "significant" does not set too high of a standard because it requires a ***meaningful*** clinical change in activities of daily living or a reduction of work restrictions. Moreover, the definition of the term "functional improvement" will be applicable to specific treatments as set forth in the MTUS, such as use of acupuncture for musculoskeletal conditions. It is clear from the text of the proposed regulations that this definition will not apply to conditions that do not result in a functional outcome, such as for example the treatment of hypertension or the treatment of diabetes where the desired outcome is to control blood pressure and blood sugar. Commenter references the discussion of "functional restoration as a goal of medical treatment that is consistent with ACOEM's philosophy" which was set forth in the December 2006 Notice of Modification to Text of Proposed Regulations (at pp. 3-4) to argue that the ACOEM Practice Guidelines do not provide for chronic treatment.	None.

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	for conditions such as chronic pain. Commenter states that over-treatment is inappropriate, but there is no scientific validity to the statement that it results in more serious adverse effects than under treatment.		Commenter's argument is misplaced. Response No. 11—Chronic Conditions, which is part of the 45-day comments chart, sets forth an explanation as to the applicability of ACOEM to chronic conditions. Moreover, the Medical Evidence Evaluation Advisory Committee will concentrate on addressing those areas of need not covered by the ACOEM Practice Guidelines. Further, the goal of evidence-based medicine is to identify optimal treatments as both over treatment and under treatment can cause harm. Each situation would require a determination of what is optimal for the patient.	
Section 9792.20(e)	Commenter opines that "functional improvement" should not supplant the traditional measure for completion of treatment. Commenter states that if the proposed regulations, through use of "functional improvement" seek to change the current standard for declaring a patient permanent and stationary, then the proposed regulations must be rejected. Commenter opines that if that is the intent of the proposed change, the regulations are a wolf in sheep's clothing. Commenter states that would appear to be a shift in philosophy as to the course of treatment, and would fundamentally alter the level of care to which workers are entitled. Commenter further states that the summary that accompanied the re-noticed proposal nearly sweeps this issue under the rug and suggests that full recovery is not a target – that workers can live and work with pain.	Bo Thoreen, Esq. December 22, 2006 Written Comment	**Disagree.** Commenter appears to indicate that Section 9792.20(e) changes the current standard for declaring a patient permanent and stationary. The statement is incorrect. The definition of maximal medical improvement is set forth in Section 9785 setting forth the reporting duties of the primary treating physician. Section 9785(a)(8) provides that "permanent and stationary status is the point when the employee has reached maximal medical improvement, meaning his or her condition is well stabilized, and unlikely to change substantially in the next year with or without medical treatment." A determination of permanent and stationary status does not preclude provision of	None.

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	Commenter concludes that ultimately, adjusting downward the threshold for when treatment ceases advances the interests of carriers only.		further medical treatment. Functional improvement is but one component to determine outcome of medical treatment. The definition of the term "functional improvement" will be applicable to specific treatments as set forth in the MTUS, such as use of acupuncture for musculoskeletal conditions. It is clear from the text of the proposed regulations that this definition will not apply to conditions that do not result in a functional outcome, such as for example the treatment of hypertension or the treatment of diabetes where the desired outcome is to control blood pressure and blood sugar.	
Section 9792.20(e)	Commenter recommends that the definition of the term "functional improvement" be moved to §9792.21(a)(2)(A) because the term only applies to the new Acupuncture Medical Treatment Guidelines.	Linda F. Atcherley President California Applicants' Attorneys Association December 22, 2006 Written Comment	**Disagree**. This definition was placed in the definitions section of the proposed regulations and not in the acupuncture section because the definition carries a more general significance and can be useful for other physical modalities. This is consistent with functional improvement expectations from other treatments or therapies targeted to improve activity limiting medical conditions. Other applicable treatments may be subject to this definition as they are added to the MTUS.	None.
Section 9792.20(e)	Commenter states that the definition of "functional improvement" contains an inappropriate use of semicolon and/or syntax error. Commenter recommends that DWC	Lachlan Taylor Commission on Health and Safety and Workers' Compensation	**Disagree.** At the outset, it is noted that the definition of "functional improvement" has been amended pursuant to a previous comment to	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING COMMENTS 1ST 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	change the syntax according to the intended meaning. Commenter believes that the definition is probably supposed to be a list of three conditions, any one of which will satisfy the definition, in the form *A* or *B* or *C*. Commenter further states that if that is the intent, "; and" should be changed to ", or". Commenter also states that if the definition is supposed to be one required condition plus either of the two additional conditions, rearrange the sentence in the form *C* and either *A* or *B*.	December 22, 2006 Written Comment	insert a comma after the phrase "physical exam." This amendment clarifies that not only the reduction in work restrictions, but also the clinically significant improvement in activities of daily living, are measured during the history and physical exam and must be documented as part of the evaluation and management visit billed under the Official Medical Fee Schedule (OMFS). With regard to the comment submitted, the commenter is incorrect in assuming that the definition sets forth a list of three conditions, any of which will satisfy the definition. The definition intends that either of the first two conditions be met, followed by meeting the third condition. It is not necessary to reverse the order of the conditions as proposed by the commenter because the meaning remains the same, and it is believed that the sentence is clear as written.	
Section 9792.20(g)	Commenter opposes the amendment to this definition to require that "medical treatment guidelines" be developed "by a multidisciplinary process." Commenter states that in the notice, the amendment is justified on the basis that the 2005 RAND report quoted a finding in an Institute of Medicine report that recommends the multidisciplinary development process. Commenter believes that this justification is misplaced because the quoted IOM report was issued in 1990, over 16 years ago, and because commenter believes	Linda F. Atcherley President California Applicants' Attorneys Association December 22, 2006 Written Comment	**Disagree**. The requirement that the guideline be reviewed by a multidisciplinary panel was added to the proposed definition based on public comments received during the 45-day comment period. The justification for the change was set forth in the Notice of Modification to Text of Proposed Regulations, and in Response No. 4-Definition of term "medical treatment guidelines," which is part of the 45-day comments	None.

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	that RAND did not endorse a multidisciplinary process, as it only found five multidisciplinary guidelines that met its minimal standards. Commenter opines that both employers and employees are best served when appropriate treatment is provided in a timely manner, and urges that the subdivision be amended to define all evidence based guidelines by deleting the reference to a multidisciplinary process.		chart. We indicated that justification for this change was based on the 2005 RAND Report at p. xviii as set forth in the ISOR at p. 20. In the ISOR, at page 20, the RAND's guidelines evaluation criteria, was set forth in pertinent part, as follows: "The fifth criterion, as contained in the second phase of the selecting criteria, i.e., that multidisciplinary clinical panels had to be involved in developing the guidelines, is of import. In its 2005 report, RAND discusses a report issued by the Institute of Medicine (IOM) as follows: "A 1990 IOM report on clinical practice guidelines considered a multidisciplinary development process to be an important component of guideline quality. The report asserted that use of a multidisciplinary team increases the likelihood that (1) all relevant scientific evidence will be considered, (2) practical problems with using the guidelines will be identified and addressed, and (3) affecting [provider] groups will see the guidelines as credible and will cooperate in implementing them [citation omitted]." (2005 RAND Report, at p. xviii.) As reflected in the 1990 IOM report, multidisciplinary involvement in the writing of medical treatment	

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			guidelines is an important element to insure the quality of the guideline. The date of the report is not probative that the report is outdated in view of commenter's lack of offering a more recent report disputing the findings of the 1990 IOM report. Moreover, commenter's belief that "RAND did not endorse a multidisciplinary process, as it only found five multidisciplinary guidelines that met its minimal standards" is without substantiation. Commenter does not reference a statement in the RAND report wherein RAND retracts from the statement in its report approving multidisciplinary panels. To the contrary, after setting forth the findings of the 1990 IOM report regarding multidisciplinary panels, RAND expresses its approval by citing more recent references and studies on multidisciplinary panels, and stating at p. xviii, as follows: "Accepted guideline-assessment tools share the requirement for a multidisciplinary development process (AGREE Collaboration, 2001; Shaneyfelt, Mayo-Smith, and Rothwangl, 1999). Also, studies suggest that multidisciplinary panels produce more-balanced interpretations of the literature than single-specialty panels do (Coulter, Adams, and Skelelle, 1995). Finally,	

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			we believe that sets of guidelines addressing diverse therapies and injuries should have input from a variety of relevant experts."	
Section 9792.20(g)	Commenter opposes the requirement that a "multidisciplinary process" be used to develop guidelines. Commenter agrees that multidisciplinary guidelines may be optimal, but opines that there are many credible, respected guidelines developed by national physician specialty organizations that are not multidisciplinary.	Joseph L. Dunn CEO/Executive Vice President California Medical Association December 22, 2006 Written Comment	**Agree.** Commenter is correct that there are many credible, respected guidelines developed by national physician specialty organizations that are not multidisciplinary. In order to recognize these guidelines, the multidisciplinary medical evidence evaluation advisory committee will evaluate them by applying the requirements of subdivision (b) of Section 9792.22 to insure that the guidelines are scientifically and evidence-based, and nationally recognized by the medical community. Further, it appears from the comment, that the proposed regulations are not clear as to the process to be used by the committee in making recommendations to revise, update or supplement the MTUS. Proposed Section 9792.23(c) has been clarified to reflect this process. See also, response to comment submitted by Linda F. Atcherley, President, California Applicants' Attorneys Association, dated December 22, 2006, above.	Proposed Section 9792.23(c) has been amended. It now states: (c) To evaluate evidence when making recommendations to revise, update or supplement the medical treatment utilization schedule, the members of the medical evidence evaluation advisory committee shall: (1) Apply the requirements of subdivision (b) of Section 9792.22 in reviewing medical treatment guidelines to insure that the guidelines are scientifically and evidence-based, and nationally recognized by the medical community; (2) Apply the ACOEM's strength of evidence rating methodology to the scientific evidence as set forth in subdivision (c) of Section 9792.21 after

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				identifying areas in the guidelines which do not meet the requirements set forth in subdivision (b) of Section 9792.21; (3) Apply in reviewing the scientific evidence, the ACOEM's strength of evidence rating methodology for treatments where there are no medical treatment guidelines or where a guideline is developed by the Administrative Director, as set forth in subdivision (c) of Section 9792.21.
Section 9792.20(g).	Commenter opposes the amendment to the definition which requires that all supplemental treatment guidelines be developed "by a multidisciplinary process." Commenter states that there are some excellent treatment guidelines that were developed by specialty societies without using a multidisciplinary process. Merely because other physicians were not involved in the development process does not necessarily invalidate the quality or appropriateness of a particular guideline	Steven J. Cattolica Carlyle Brakensiek Advocal December 22, 2006 Written Comment	**Agree.** See response to Joseph L. Dunn, CEO/Executive Vice President, California Medical Association, dated December 22, 2006, above. See also, response to comment submitted by Linda F. Atcherley, President, California Applicants' Attorneys Association, dated December 22, 2006, above.	None.
Section 9792.20(g)	Commenter objects to the proposed amendments in this definition to require that medical treatment guidelines be "…revised within the last five years," and be "…developed by a multidisciplinary process." Commenter states that this language would undermine a recent court decision that allowed	John Bueler, Jr., DC President California Chiropractic Association December 22, 2006 Written Comment	**Disagree.** The requirement that the medical treatment guideline be "revised within the last five years" was the result of comments requesting that the definition limit the effective date of the treatment guideline in order to insure currency.	None.

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	a doctor of chiropractic to cite the Mercy guidelines to support the medical need for treatment. Commenter opines that although Mercy is a specialty guideline that has not been updated in many years, many of its prescriptions for treatment are still consistent with today's best practices.		We agreed with the comment because we believe that it is important to prevent the use of outdated guidelines to guide the provision of medical treatment. We required that the guideline be revised within the last five years based on the requirements of the National Guideline Clearinghouse (NGC)'s inclusion criteria at http://www.guideline.gov/about/inclusion.aspx. With regard to the comment that there is case law allowing for the use of the Mercy Guideline, commenter does not provide a citation to that case, thus we are unable to determine the factual circumstances of that decision. With regard to the remaining comment, see response to comment submitted by Linda F. Atcherley, President, California Applicants' Attorneys Association, dated December 22, 2006, above. Moreover, commenter cites the requirement that the medical treatment guidelines be developed by "a multidisciplinary process," but does not offer any comments in that regard. In this regard, see See, response to Joseph L. Dunn, CEO/Executive Vice President, California Medical Association, dated December 22, 2006, above.	
Section 9792.20(g)	Commenter states that the definition of "medical treatment guidelines" needs attention to timing of when "most recent" is determined	Lachlan Taylor Commission on Health and Safety and Workers'	**Disagree**. Most recent guideline implies that there is more than one guideline in existence and the latest	None.

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	(at time of service, or at time of judicial review, or when?). Commenter inquires as to when a guideline is "revised" (on publication date, or last meeting of the guideline revision committee, or when?). Commenter also inquires as to when "the last five years" is calculated (five years prior to date of request, date of service, date of UR decision, date of judicial review, or when?).	Compensation December 22, 2006 Written Comment	one is selected. Revision date of a document, including a guideline, is always set forth in the document. The five year requirement refers to the date of the guideline. These requirements are clear from the language of the regulation. There is no need to add further language to the definition.	
Section 9792.20(h)	Commenter states that the proposed regulation is unduly reliant on MEDLINE. Commenter further states that while MEDLINE may be the largest publisher, there is no reason to effectively make it the only publisher when making an assessment as to whether something is "scientifically based." Commenter opines that this unduly limits the universe of those reports that are, in fact, scientifically-based. Commenter further opines that while MEDLINE can serve as a touchstone, it ought not to serve as the sole arbiter of what is or is not "scientifically-based."	Bo Thoreen, Esq. December 22, 2006 Written Comment	**Disagree.** Section 9792.20(h) sets forth the definition for the term MEDLINE. The term is defined as "the largest component of PubMed, the U.S. National Library of Medicine's database of biomedical citations and abstracts that is searchable on the Web." MEDLINE functions as an important resource for biomedical researchers from all over the world as it facilitates evidence-based medicine. The National Library of Medicine (NLM) works with the Cochrane Center to improve access to clinical trials information in MEDLINE. The NECC coordinates the ongoing efforts of various Cochrane Centers, Review Groups, and others collaborating to identify citations to be enhanced and annually gives this information to NLM, and thus can be found in MEDLINE. Most systematic review articles published nowadays build on extensive searches of MEDLINE to identify articles that might be useful in the review. Many articles mention the	None.

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			terms that have been used to search MEDLINE, so that the search is reproducible by other scientists. Contrary to commenter's opinion, MEDLINE is inclusive of the relevant knowledge useful to support scientifically-based evidence. (See, http://en.wikipedia.org/wiki/Medline, as of the date of the March 2007 2nd 15-Day Notice.)	
Section 9792.20(i)	Commenter opposes the definition of "nationally recognized" because it prohibits the use of internationally accepted treatment guidelines. The World Health Organization is in the process of developing comprehensive treatment guidelines that will be recognized, but may not be immediately "in use" by one or more US states or the US federal government. This proposed definition would arbitrarily preclude these guidelines from being used under California's workers' compensation system even if they meet every other criterion as specified in the proposed regulations.	John Bueler, Jr., DC President California Chiropractic Association December 22, 2006 Written Comment	**Disagree**. The commenter offers no basis for his opinion that if the World Health Organization (WHO) develops treatment guidelines, the California MTUS will be precluded from using internationally accepted treatment guidelines because of its definition of the term "nationally recognized." The WHO has 193 member-states, including all UN member-states with the exception of two member-states. The United States (U.S.) is a member of WHO, and by its participation in WHO as a nation, it nationally recognizes WHO and its product. Although we cannot predict the future, it is likely that a guideline developed by WHO with U.S. participation is likely to be used by the U.S. federal government as developed and approved by the members of WHO. Thus any developed medical treatment guidelines by WHO, would be nationally recognized, and the definition of "nationally recognized" in our proposed regulations would	None.

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			apply. Regardless, of whether the guideline is nationally recognized, the guideline also must be evidence and scientifically-based to meet the requirements of the proposed regulations.	
Section 9792.20(i)	Commenter states that use of the definition of the term "nationally recognized" further highlights the reliance on the ACOEM guidelines despite the use of the new label – MTUS. Commenter opines that in shifting from "generally recognized" to "nationally recognized" the proposed regulation requires still more from a physician whose course of treatment deviates from the ACOEM guidelines. Setting this high threshold assures that the ACOEM guidelines will more likely be the de facto rule. Commenter indicates that the DWC should recall that physicians are trained to comply with national standards of care at every level of their education. Commenter opines that a physician who relies on the ACOEM guidelines to pass board exams would likely fail. Commenter further states that MEDLINE publications do not define the standard of care. The proposal makes ACOEM the rule and requires physicians – trained to a national standard – to justify perfectly reasonable courses of treatment that may deviate from the strictures of ACOEM.	Bo Thoreen, Esq. December 22, 2006 Written Comment	**Disagree.** The comment does not address the proposed changes made to the regulations subject to the 15-day notice. Response No. 4—Definition of the term "medical treatment guidelines," which is part of the 45-day comment chart, clearly addresses the comments raised by the commenter. Commenter's opinion that a physician that is trained to comply with national standards of care at every level of his or her education would fail board exams if the physician relied on the ACOEM guidelines to pass the board exams, is irrelevant. Although using the ACOEM Practice Guidelines as a study guide could help a physician pass certain questions on a board examination, examinations generally cover material that is beyond the scope of any treatment guideline. For instance, the boards on occupational medicine have questions on statistics which would never be included in a practice guideline. ACOEM presents current guidelines chosen with the specific purpose of compliance with the requirements of Labor Code section 5397.27, which requires that the MTUS incorporate evidence-	None.

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			based, peer-reviewed, nationally recognized standards of care that address, at a minimum, the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers' compensation cases. Moreover, the MTUS and the statute provide that any physician who disagrees with the guidelines set forth in the MTUS, including ACOEM, may present other evidence to refute the guidelines.	
Section 9792.20(j)	Commenter suggests amending the proposed definition of the term "peer reviewed" to state: "Peer reviewed" means that a medical study's content, methodology and results have been evaluated and approved prior to publication by an editorial board of qualified physician experts.	Joseph L. Dunn CEO/Executive Vice President California Medical Association December 22, 2006 Written Comment	**Disagree**. The suggested requirement that the experts be physicians is too narrow. The definition envisions that other experts would qualify under the definition. For example, academic research experts.	None.
Section 9792.20(k)	Commenter continues to have concern that the definition of "scientifically based" is related to a web site. MEDLINE is a clearinghouse only and the information contained therein is not necessarily "scientifically based." Commenter suggests the following definition: "involves the application of rigorous, systematic, and objective procedures to obtain reliable and valid knowledge relevant to medical testing, diagnosis and treatment; involves rigorous data analyses that are adequate to test the stated hypotheses and justify the general conclusions drawn; and, has been accepted through a comparably rigorous, objective, and scientific review."	Tina Coakley Legislative & Regulatory Analyst The Boeing Company December 21, 2006 Written Comment	**Disagree.** DWC does not believe that the definition of "scientifically based" should contain the language as described by commenter. DWC agrees that a simple reference in MEDLINE does not indicate its scientific rigor. For that reason, Section 9792.22(c)(1) sets forth the strength of evidence which must be used to evaluate the medical literature. Moreover, see response to comment submitted by Bo Thoreen, Esq., dated December 22, 2006, regarding Section 9792.20(h), set forth above.	None.

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Section 9792.21(a)(1)	Commenter believes that language should be revised to read as follows: "(a)(1) The American College of Occupational and Environmental Medicine's Occupational Medicine Practice Guidelines (ACOEM Practice Guidelines) 2nd Edition (2004). A copy may be obtained from American College of Occupational and Environmental Medicine, 25 Northwest Point Blvd., Suite 700, Elk Grove Village, Illinois, 60007-1030 (www.acoem.org)."	Pat O'Connor Director of Government Affairs – ACOEM December 22, 2006 Written Comment	**Agree**. Section 9792.21 (a)(1) of the proposed regulations should be amended to reflect the correct source where a copy of the ACOEM Practice Guidelines, 2nd Edition, may be obtained.	Section 9792.21(a)(1) has been amended to reflect that a copy of the ACOEM Practice Guidelines, 2nd Edition, may be obtained from American College of Occupational and Environmental Medicine, 25 Northwest Point Blvd., Suite 700, Elk Grove Village, Illinois, 60007-1030 (www.acoem.org)
Section 9792.21(a)(l)	Commenter again requests that the Division consider adding after "Second Edition (2005)" "or the most recent publication" to preclude the Division of Workers' Compensation having to update this section at a later date.	Tina Coakley Legislative & Regulatory Analyst The Boeing Company December 21, 2006 Written Comment	**Disagree.** The comment does not address the proposed changes made to the regulations subject to the 15-day notice. This issue was thoroughly addressed in Response No. 1—Adoption by Incorporation by Reference an Existing Document and Any Future Updates, which is part of the 45-day comment period chart.	None.
Section 9792.21(a)(2)	Within the proposed strength of evidence provisions, it is suggested that the Official Disability Guidelines – Treatment in Workers' Compensation (ODG-TWC) recommendations regarding acupuncture be adopted in its place. Commenter believes that this should be revised to reflect an objective, scientific evidence basis because this would be more consistent with adopting any treatment guideline recommendations based on evidence as opposed to consensus basis.	Kelly M. Weigand, Esq. First Health December 20, 2006 Written Comment	**Disagree.** Although the language set forth in the ODG-TWC Guidelines relating to Acupuncture is similar to that found in the Colorado State guidelines and is evidence-based, DWC believes that it is more appropriate to craft our acupuncture medical treatment guidelines based on the guidelines of the State of Colorado because their guidelines went through a multidisciplinary panel review (see, *State of Colorado, Division of Workers' Compensation, Medical Treatment Guidelines—Medical Treatment Guidelines*	None.

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			Update Process, wherein it is stated: "[n]ew guideline processes … include … a multidisciplinary Advisory Panel to provide clinical feed back to the Task Force and the Division), and rulemaking process. (See also, State of Colorado, Division of Workers' Compensation, Medical Treatment Guidelines, General Information, http://www.coworkforce.com/dwc/DivisionResources/mtgsummarybriefintro.pdf)	
Section 9792.21(a)(2)	Commenter is concerned about potential collateral effects of incorporating acupuncture as an allowable treatment. Commenter states that he is aware, anecdotally, that upon referral, an acupuncturist may exceed their scope of practice and add non-acupuncture modalities (e.g. massage, exercise, herbal therapy) to the therapeutic regimen. It is likely, given the addition of acupuncture as allowable treatment, that more acupuncturists will assume control of more cases. Commenter hopes that what is now an observable but still occasional overstepping of professional scope does not become an all-out trend.	Steven C. Schumann, MD Legislative Chair Western Occupational & Environmental Medical Association (WOEMA) December 22, 2006 Written Comment	**Disagree.** Labor Code section 4600 provides that the injured worker is entitled to acupuncture as reasonably required medical treatment to cure or relieve the effects of the industrial injury. Further, Labor Code section 5307.27 requires that the medical treatment utilization schedule address, at a minimum, the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers' compensation cases, including acupuncture. Therefore, acupuncture must be included in the MTUS. Scope of practice is defined as regulated by the various licensing boards in California and is not a subject of these proposed regulations.	None.
Section 9792.21(a)(2)	Commenter states that DWC's determination to anchor the MTUS with the ACOEM guidelines and to augment that foundation	Brenda Ramirez Claims and Medical Director	**Agree in part.** DWC agrees it is our goal to anchor the MTUS with the ACOEM guidelines and to augment	None.

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	with additional guidelines of proven value, as determined by the expert physician panel, establishes a sound methodology and a reasonable process for the development of the schedule. Commenter states that the proposed regulations establish both the preeminence of the ACOEM methodology and philosophy and the process to review and adopt guidelines of comparable quality.	Michael McClain General Counsel & Vice President Alex Swedlow Executive Vice President California Workers' Compensation Institute December 22, 2006 Written Comment	that foundation with additional guidelines of proven value, as determined by the expert physician panel. DWC agrees that this establishes a sound methodology and a reasonable process for the development of the schedule. The goal of the proposed regulations is to establish both the preeminence of the ACOEM methodology and philosophy and the process to review and adopt guidelines of comparable quality.	
	Commenter requests, however, that the proposed acupuncture guidelines be withdrawn, evaluated by the Medical Evidence Evaluation Advisory Committee, and reconsidered in the future. Commenter opines that the inclusion of acupuncture medical treatment guidelines at this time is premature. Commenter argues that the adoption of the acupuncture medical treatment guidelines is contrary to having incorporated the philosophy of evidence-based medicine, as mandated by the statute, and having initiated the process to evaluate additional treatment guidelines, as suggested by the statute, because the acupuncture medical treatment guidelines have not been vetted by the expert physician panel, and are proposed to supersede the ACOEM Practice Guidelines. Commenter recommends conducting both processes before the first set of supplemental medical protocols is adopted augmenting the ACOEM guidelines.		**Disagree.** The Colorado guidelines are evidence based. *The State of Colorado, Division of Workers' Compensation—Medical Treatment Guideline Update Process* states: "[i]nitially, during 'the internal review' stage, current medical literature related to the guideline is systematically reviewed, critiqued, and graded by the Division and the multidisciplinary-task force." Thus, it meets the statutory requirement that the guideline be evidence-based. It should be noted that the statute does not require that medical treatment guidelines have to be vetted by an expert physician panel. However, Colorado did have a multidisciplinary panel involved in formulating their guideline. (See also, State of Colorado, Division of Workers' Compensation, *Medical Treatment Guidelines, Evidence-*	None.

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	Commenter references Response No. 14—Acupuncture Medical Treatment Guidelines, which is part of the 45-day comments chart, which sets forth the reasons for adopting the acupuncture medical treatment guidelines. Commenter states that DWC is careful to note that Labor Code section 5307.27, which is founded upon evidence-based medicine, defines reasonable medical care under Labor Code section 4600. Commenter adds that any physician providing medical care of any type under these provisions is now constrained by the medical treatment utilization schedule. Commenter opines that while acupuncturists are included in section 4600, their treatment protocols are defined and prescribed by the treatment schedule. Commenter argues that acupuncture is not a common form of treatment in workers' compensation cases. Commenter further argues that in meeting the requirements of Labor Code section 5307.27 by determining whether DWC is statutorily obligated to address the appropriateness of acupuncture as one of "all treatment procedures and modalities commonly performed in workers' compensation cases," DWC must begin with the question of whether acupuncture is a common form of treatment in workers' compensation cases. Commenter submits that it is not. Commenter states that pre- and post-reform acupuncture account for less than 1% of the medical care provided to injured workers in California. Commenter states that acupuncture is a rarely used modality that is not supported by high quality medical		*Based Parameters*, which has been added to the rulemaking file.) **Disagree.** According to Workers' Compensation Insurance Rating Bureau (WCIRB) reports of acupuncture costs paid by insurers between 2001 and 2005, acupuncture represented a percentage between 1.1% to 1.4% of all medical costs paid. However, these payments exceeded payments to emergency room physicians, dentists, neurosurgeons, hand surgeons, podiatrists, dermatologists, plastic surgeons, pulmonary diseases, ophthalmology, pathology, and optometry for each group for the same years. (See, 2005 *California Workers' Compensation Losses and Expenses*, Dated June 23, 2006, at p. 9.) Based on commenter's reasoning,	None.

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	evidence.		none of these medical services should be allowed in the MTUS either. Moreover, some of these services were adopted by the legislature during the reform legislation when ACOEM was adopted by SB 228. For instance, ACOEM contains an entire chapter on the eye which is under the purview of ophthalmology and optometry.	
	Commenter argues that the Acupuncture Medical Treatment Guideline is not evidence-based. Commenter states that DWC cites the relevant portions of the ACOEM Practice Guidelines, Second Edition and the more recent article: *Acupuncture-Medical Literature Analysis and Recommendations*, published in the APG "Insights," Winter 2005, discussing the appropriate use of acupuncture and whether its use is supported by medical, scientific evidence. Commenter states that DWC's rationale also refers to (without citing) the Colorado guidelines and the medical evidence on which those are based. Commenter states that DWC concludes that ACOEM now agrees that acupuncture is "an optional intervention." Commenter argues that DWC, however, makes no reference to the Strength of Evidence Ratings and no determination of whether the proposed acupuncture guidelines meet the standards established in the proposed treatment schedule. Commenter adds that regardless, the		**Disagree.** In the Notice of Modification of Text of the Proposed Regulations issued December 2006, and in Response No. 14—Acupuncture Medical Treatment Guidelines, which is part of the 45-day comments chart, DWC set forth its justification for the adoption of the Acupuncture Medical Treatment Guidelines. Although the reasons for the adoption of the Acupuncture Medical Treatment Guidelines are set forth in those documents in detail, it is necessary to summarize the relevant portions of why the guidelines were adopted, and the reasons DWC proposes the guidelines are evidence-based. First, it is important to note that DWC recognizes that Labor Code section 4600 provides that the injured worker is entitled to acupuncture as reasonably required medical treatment to cure or relieve the	None.

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	acupuncture guideline will not be added merely as an "optional intervention," it will be given equal weight with evidence-based medical treatment standards of the highest quality. As a result, the acupuncture guideline will be given the legal weight of the presumption of correctness under Labor Code section 4604.5. Commenter also states that there can be no question that the use of the medical treatment utilization schedule to expand the definition of reasonable medical care under section 4600 is founded on the philosophy of evidence-based medicine in order to deliver the highest quality medical care to injured workers. Commenter states that the criticism by DWC of the Commission's recommendation to consider a patchwork of discrete and independent treatment guidelines is still valid. No new scientific evidence, data, or analysis has intervened to cast doubt on the DWC's initial criticism of that approach issued in July of this year. Commenter concludes that the proposed regulations attempt to cure the potential for conflicting standards by allowing these low-grade guidelines to supersede the high-grade evidence produced in support of the ACOEM guidelines. Before that decision becomes final, commenter recommends that the AD reexamine the supporting evidence-base of the proposed acupuncture guidelines and harmonize those guidelines, to the greatest extent possible, with the recommendations of the ACOEM Practice Guidelines.		effects of the industrial injury. Second, it is necessary to note that Labor Code section 5307.27 requires that the medical treatment utilization schedule *address, at a minimum,* the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers' compensation cases. Third, upon closer review, of the ACOEM Practice Guidelines, Second Edition, DWC determined that these guidelines do not address acupuncture thoroughly. Fourth, we received numerous comments arguing that the ACOEM Practice Guidelines do not address acupuncture properly, and requesting that we adopt an acupuncture guideline. After consideration of all of the elements set forth above, and taking into consideration Labor Code section 4600 and Labor Code section 5307.27, the Acting Administrative Director determined that in order to implement, interpret, and make specific Labor Code section 5307.27, it is necessary to harmonize the statutes (Labor Code section 4600 and Labor Code section 5307.27.) That is, acupuncture is the treatment that is not covered as well in the ACOEM Practice Guidelines yet access to acupuncture is required by Labor Code section 4600. In this	

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	Commenter further argues that the Acupuncture Medical Treatment Guidelines should be reviewed by the Medical Evidence Evaluation Advisory Committee. Commenter states that in the initial structure of the regulatory scheme for the treatment schedule, DWC created the process by which the schedule will be augmented with additional medical treatment guidelines. Commenter further states that Section 9792.23 creates an advisory committee to provide expert medical counsel on the development of the treatment schedule. Commenter references the rationale for adopting the Acupuncture Medical Treatment Guidelines set forth in Response No. 14 attached to the 45-day comments and responses chart. Commenter states DWC confirmed the importance of harmonizing the treatment schedule, quoting: "ACOEM remains the foundation for the MTUS, and any supplemental guidelines including the Acupuncture Medical Treatment Guidelines, must be fitted to ACOEM. This approach avoids conflict and the negation of the presumption of correctness pursuant to Labor Code section 4604.5(a)."		regard, the Acting Administrative Director determined that it is appropriate to adopt an Acupuncture Medical Treatment Guideline as a first priority in supplementing the MTUS. **Agree in part.** The Acupuncture Medical Treatment Guidelines were developed in relationship to the ACOEM Practice Guidelines' chapters to address those complaints addressed in those chapters. The Acupuncture Medical Treatment Guidelines as set forth in the proposed regulations did not go through a review process for the reasons set forth above and because it is crafted based on the Colorado Guidelines, which went through formal rulemaking. (See, State of Colorado, Division of Workers' Compensation, Medical Treatment Guidelines, General Information, http://www.coworkforce.com/dwc/DivisionResources/mtgsummarybriefintro.pdf.) The advisory committee is not required by statute. DWC has determined that using an advisory committee is important. However, as Colorado vetted the Acupuncture Guidelines through an advisory committee, DWC has determined that this process suffices. (See, State of Colorado, Division of Workers' Compensation, *Medical Treatment*	None.

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	Commenter also references Response 6—ACOEM Meets the Requirements of Labor Code Section 5307.27. Commenter states that in that response, DWC noted the need to ensure an ongoing developmental process for the treatment schedule, quoting: "… although ACOEM Practice Guidelines met the minimum requirement, these guidelines do not cover all treatment procedures and modalities commonly performed in workers' compensation in California. These subjects will be evaluated by the Medical Evidence Evaluation Advisory Committee (advisory committee). This advisory committee will be created by way of these proposed regulations to review the medical literature in these areas to determine if new evidence should be used to supplement the ACOEM Practice Guidelines as adopted in the medical treatment utilization schedule." Commenter concludes by expressing support for such a diverse, expert, advisory panel of physicians and recommends that for the consideration of the first set of supplemental guidelines, it is essential that this process be allowed to work, both to examine the evidence and consider the appropriate modalities to be used.		*Guidelines, Medical Treatment Guidelines Update Process*, which has been added to the rulemaking file.) We note, however, that the Acupuncture Medical Treatment Guidelines are not all inclusive. Indeed, the guidelines were developed to match the ACOEM chapters. There are areas which may need to be developed. In developing these areas, DWC will use the committee to review proposed supplements and/or revisions to the Acupuncture Medical Treatment Guidelines. The committee will be using the Strength of Evidence Rating set forth in Section 9792.22(c) when developing a guideline or when reviewing a guideline's evidence-base. The committee will be reviewing other areas outside of acupuncture as well and using the committee and the strength of evidence rating to address any gaps in the ACOEM Practice Guidelines.	
Section 9792.21(a)(2)	Commenter states that he is not opposed to DWC's adoption of the acupuncture medical treatment guidelines described in 9792.21(a)(2), but he is concerned that the guidelines do not fully comply with the	Samuel Sorich President Association of California Insurance Companies December 22, 2006	**Disagree**. See response to comment submitted by CWCI, dated December 22, 2006, on the argument that the Acupuncture Medical Treatment Guidelines are not evidence-based.	None.

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	principle that treatment guidelines must be evidence-based. Labor Code Section 5307.27 requires that the medical treatment utilization schedule must incorporate evidence-based standards. Commenter is not convinced that the proposed acupuncture guidelines satisfy this requirement. Commenter believes that the adoption of the acupuncture guidelines should not be used as a precedent to justify the adoption of treatment guidelines that are not evidence-based.	Written Comment	With regard to the remaining comment, DWC notes that the Medical Evidence Evaluation Advisory Committee will be reviewing other guidelines to address any gaps in the ACOEM Practice Guidelines for purposes of supplementing the MTUS, and the committee will be using the Strength of Evidence Rating set forth in Section 9792.22(c)	
Section 9792.21(a)(2)	Commenter states that since 2004, the ACOEM Practice Guidelines have been implemented in the California workers' compensation system as presumptively correct on an interim basis. Commenter further states that as cited on many occasions—by patients, providers, and by the RAND Corporation's evaluation of the guideline—acupuncture is among the topics that the guideline addresses, as the RAND study puts it, "minimally or not at all." Commenter opines that this has resulted in widespread denials of acupuncture treatment and in the de facto elimination of acupuncture as a readily accessible treatment modality within the workers' compensation system. Commenter states that the California Oriental Medicine Association applauds DWC's addition of Subdivision 9792.21(a)(2)—Acupuncture Medical Treatment Guidelines, into the proposed regulations.	Bill Mosca, LAc Executive Director California Oriental Medicine Association December 22, 2006 Written Comment	**Agree in part.** DWC accepts the comment about the adoption of the Acupuncture Medical Treatment Guidelines. We disagree with the remaining portion of the comment as no factual information has been presented to DWC to prove or disprove Commenter's opinion that the adoption of the ACOEM Practice Guidelines "has resulted in widespread denials of acupuncture treatment and in the de facto elimination of acupuncture as a readily accessible treatment modality within the workers' compensation system."	None.
Section 9792.21(a)(2)	Commenter states that while the new Acupuncture Medical Treatment Guidelines address many of the deficiencies of the ACOEM Practice Guidelines, he remains	Bill Mosca, LAc Executive Director California Oriental Medicine Association	**Agree in part.** At the outset, it is noted that in the December 2006 Notice of Modification of Text of the Proposed Regulations, and in	Section 9792.21(a)(2)(C)(iv) has been deleted from the text of the proposed

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	concerned with DWC's departure from the Colorado State Guidelines in some respects in view of DWC's own statement that the Colorado guidelines have been subject to multidisciplinary review. Commenter argues that when comparing Subdivision 9792.21(a)(2)(C) to the original counterpart language in Colorado, it is apparent that a more restrictive frequency and duration standard is being proposed in the California regulations. Commenter notes that subdivision (a)(2)(C)(i) indicates a "time to produce functional improvement" of 3 to 6 treatments where "functional improvement" is somewhat, in commenter's opinion, narrowly defined in Subdivision 9792.20(e). Commenter then argues that the Colorado regulations, on the other hand, require only that the acupuncture treatments "produce effect" within the first 3 to 6 treatments. Commenter argues that in the proposed regulations, "functional improvement," as defined, must be measurable and documented as part of an evaluation and management visit; whereas, "effect," as required in the Colorado guidelines, could be temporary improvement that is not sustained long enough to be measurable in an evaluation and management visit. Commenter further argues that in the proposed regulations, "functional improvement" must produce a "reduction in the dependency on continued medical treatment," while in the Colorado guidelines, therapeutic "effect" may be achieved without a reduction in dependency on continuing	December 22, 2006 Written Comment	Response No. 14—Acupuncture Medical Treatment Guidelines, which is part of the 45-day comments chart, DWC set forth its justification for the adoption of the Acupuncture Medical Treatment Guidelines. We stated in our Notice and Response No. 14 that upon review of Colorado's guidelines on acupuncture, it was determined that these guidelines were more on point with the requirements of Labor Code section 5307.27. The Acupuncture Medical Treatment Guidelines were crafted based on the Colorado Acupuncture Guidelines, and taking into consideration ACOEM's APG Insights, wherein, as indicted above, ACOEM reviewed the medical literature and updated its position on the reasonableness of acupuncture treatment as an optional intervention. DWC further indicated that although the Acupuncture Medical Treatment Guidelines were crafted based on the Colorado Guidelines, DWC did not adopt their guidelines in their entirety to avoid conflict with the presumption of correctness set forth in Labor Code section 4604.5(a). As previously indicated, ACOEM remains the foundation for the MTUS, and any supplemental guidelines including the Acupuncture Medical Treatment Guidelines, has to	regulations.

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	treatment. Commenter continues to argue that the substitution of "functional improvement" in the proposed regulations for "effect" in the Colorado guidelines creates significantly more ambiguity and inconsistency in the proposed regulation than in the Colorado guidelines. Commenter offers the example of, Subdivision 9792.21(a)(2)(D), wherein it indicates that acupuncture treatments "may be extended if functional improvement is documented." Commenter assumes that this extension is beyond the maximum duration of 14 treatments indicated in Subdivision 9792.21(a)(2)(C)(iv). Commenter argues that given that functional improvement appears to be required within the first 3 to 6 treatments [Subdivision 9792.21(a)(2)(C)(i)], it is not clear if acupuncture treatment would be disallowed after 3 to 6 treatments if functional improvement has not been documented. Commenter opines that as written, there is a logical inconsistency between Section 9792.21(a)(2)(C) and Section 9792.21(a)(2)(D). Commenter argues that if functional improvement must be produced within the first 3 to 6 treatments, then there will almost certainly be functional improvement at the 14-treatment mark relative to the initiation of acupuncture treatment. Commenter adds that if so, the 14-treatment maximum duration is effectively nullified, and a de facto maximum duration of 3 to 6 treatments without functional improvement is established.		be fitted to ACOEM as it provides the medical treatment framework for the MTUS appropriate for those conditions covered by ACOEM. Commenter objects to the language contained in the proposed regulations at Section 9792.21(a)(2)(D) stating that "[a]cupuncture treatments may be extended if objective functional improvement is documented." Commenter requests that the language be changed to be consistent with the language in the Colorado State guidelines, which require that "the acupuncture produce effect." **We disagree.** DWC indicated in its Notice and Response No. 14 that the acupuncture medical treatment guidelines were crafted to be more consistent with the philosophy of functional restoration as a goal of medical treatment in the ACOEM Practice Guidelines. The ACOEM Practice Guidelines provide that the "[p]atient and clinician should remain focused on the ultimate goal of rehabilitation leading to optimal functional recovery, decreased healthcare utilization, and maximal self-actualization. (ACOEM, at p. 106.) For example, the ACOEM Practice Guidelines, state at page 89, that "[t]he first step in managing delayed recovery is to document the patient's current state of functional	

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	Commenter concludes that as a clinical practitioner of acupuncture, he finds 3 to 6 treatments to be an exceedingly short period of time to produce consistent "functional improvement" as defined in the proposed regulation. Commenter opines that while this is a reasonable window in which to achieve observable "effect," acupuncture has a slower initial time of action than many biomedical interventions. Commenter adds that acupuncture activates the innate healing capacity of the body, and that although acupuncture carries significantly lower risks of adverse events, this process is not as immediate as, for example, pharmaceutical or surgical interventions. Commenter concludes that to resolve the issues outlined above, he recommends the adoption of the following amended language for Section 9792.21(a)(2): *(C) Frequency and duration of acupuncture or acupuncture with electrical stimulation may be performed as follows:* *(i) Time to produce ~~functional improvement~~ effect: 3 to 6 treatments.* *(ii) Frequency: 1 to 3 times per week* *(iii) Optimum duration: 1 to 2 months* *(iv) Maximum duration: 14 treatments.* *(D) Acupuncture treatments may be extended beyond the maximum duration indicated in Subdivision 9792.21(a)(2)(C) if functional improvement is documented as*		ability (including activities of daily living) and the recovery trajectory to date as a timeline." Assessing activities of daily living is a component of the AMA Guides in addition to other objective methods. Moreover, Colorado State uses the phrase "time to produce effect" repeatedly throughout all of their guidelines, including non-acupuncture modalities (e.g., Low Back Pain Guideline, Exhibit 1, page no. 19, under section entitled: Therapeutic Spinal Injections—which also uses the phrase "time to produce effect"). Furthermore, the Colorado State Acupuncture Guidelines specify at Low Back Pain Guideline, Exhibit 1, page 19 on section entitled: Acupuncture—that "any of the … acupuncture treatments may [be] extend[ed] longer if objective functional gains can be documented." Thus, the desired effect in the Colorado State Guidelines on Acupuncture is functional gain. Therefore, commenter is incorrect in stating that the proposed California standard is more restrictive than the Colorado State standard. **We agree**, however, that Section 9792.21(a)(2) is confusing as presently drafted. Section 9792.21(a)(2)(C)(iii) allows for 3 to	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING COMMENTS 1ST 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	defined in Section 9792.20(e). Commenter believes that this revised language will preserve consistency with the philosophy of functional restoration as a goal of medical treatment in the ACOEM Practice Guidelines while significantly disambiguating the proposed regulation.		6 acupuncture treatments, and Section 9792.21(a)(2)(C)(iv) allows for 14 treatments, all subject to functional improvement pursuant to Section 9792.21(a)(2)(D). It appears, however, that Section 9792.21(a)(2)(C)(iv) allowing for 14 treatments maximum, is confusing because the treatment may be continued upon a showing of functional improvement after the initial series of treatments under Section 9792.21(a)(2)(C)(iii) and Section 9792.21(a)(2)(C)(iv) might be interpreted to constitute a cap, which is not the intention of the proposed regulations. The requirement that acupuncture achieve functional improvement serves to appropriately justify continued acupuncture treatment as this would lead to a clinically significant improvement in activities of daily living or a reduction in work restrictions …, and a reduction in the dependency on continued medical treatment. Accordingly, Section 9792.21(a)(2)(C)(iv) has been deleted from the regulations for clarification purposes.	
Section 9792.21(a)(2)(C)(i)	Commenter requests that the time allotted to produce functional improvement be increased from 3-6 treatments to 6-8 treatments. Commenter states that it should be noted that usually acupuncture treatment is recommended after the patient has been seen by a western medicine physician and chronic	Sandra Carey of Carey and Associates on behalf of the Council of Acupuncture And Oriental Medicine Associations December 22, 2006	**Disagree**. Commenter requests that the time allotted to produce functional improvement be increased from 3-6 treatments to 6-8 treatments on the basis that "there is accumulated evidence-based research from the National Institutes of	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING COMMENTS 1ST 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	conditions typically require more than the 3-6 on-average treatments to show functional improvement. Commenter states that there is accumulated evidence-based research from the National Institutes of Health, as well as a large body of experience consistently showing that an average of 6-8 treatments lead to physiological effective response at the interval of 2-3 times/week (or every 24-72 hours). Commenter further states that allowing a proven reasonable treatment schedule of 6-8 treatments and the functional improvement that results from such a schedule, will in the long run save considerable costs, both from the perspective of lasting relief (as opposed to intermittent relief rendered with the 3-6 treatment allotment), as well as saving the cost of utilization review fees.	Written Comment	Health, as well as a large body of experience consistently showing that an average of 6-8 treatments lead to physiological effective response." In DWC's Notice and Response No. 14, DWC noted ACOEM's article entitled *Acupuncture-Medical Literature Analysis and Recommendations*, published in the APG Insights, Winter 2005 (which has been added to the documents relied upon in the formal rulemaking file), at p. 2, wherein ACOEM performs an interim review of the scientific literature on acupuncture, and updates its position on the reasonableness of acupuncture treatment. DWC further noted, however, that the ACOEM's APG Insights, at page 10, states "[t]he literature does not provide guidance regarding what number of treatments would ultimately be appropriate, but if patients have demonstrated evidence of ongoing improvement by the sixth treatment, completion of another six treatments would appear reasonable." Based on ACOEM's recent systematic review of acupuncture scientific evidence as reflected in the 2005 Winter APG Insights, "the literature does not provide guidance regarding what number of treatments would ultimately be appropriate," and the comment that there is accumulated evidence-based research showing	

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			that an average of 6-8 treatments leads to physiological effective response is without basis. Moreover, the statute requires evidence-based treatment (Labor Code section 5307.27), and experience alone does not meet the requirements of the statute.	
Section 9792.21(a)(2)(D)	Commenter states that although she believes the specific treatment recommendations in the acupuncture guidelines should be higher, she strongly supports the inclusion of acupuncture guidelines in these regulations. Commenter urges DWC to consider adding specific guidelines for other areas and modalities that are not adequately covered by the ACOEM Practice Guidelines. Commenter indicates that as cited in the Notice on page 10, the CHSWC report on treatment guidelines concluded that "[n]umerous gaps and weaknesses in the ACOEM or any other existing set of guidelines will have to be filled by reliance on other guidelines." Commenter states that unfortunately, the lack of acupuncture guidelines is not the sole "gap or weakness" in the ACOEM Guidelines, and it is extremely important to injured workers and to the efficient operation of the workers' compensation system that a credible and comprehensive set of treatment guidelines be adopted as soon as possible.	Linda F. Atcherley President California Applicants' Attorneys Association December 22, 2006 Written Comment	**Agree in part.** DWC **agrees** with the comment supporting the inclusion of acupuncture guidelines in the proposed regulations. Moreover, DWC agrees that there is a need to add specific guidelines for other areas and modalities that are not adequately covered by the ACOEM Practice Guidelines. This will be accomplished with advice from the Medical Evidence Evaluation Advisory Committee.	None.
	Commenter requests that Section 9792.21(a)(2)(D) be amended to provide that acupuncture treatments may be extended where necessary to prevent further functional limitations or to maintain current functional		**Disagree** with the request that Section 9792.21(a)(2)(D) be amended to provide that acupuncture treatments may be extended where necessary to prevent further	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING COMMENTS 1ST 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	capacity. Commenter opines that these changes recognize that the statutory mandate in Labor Code section 4600 is the provision of treatment "that is reasonably required to cure or relieve the injured worker. .. ." and that many injured workers will experience continuing physical and health problems for their entire lifetime. Commenter states that for these workers, "functional improvement" may not be possible, but further deterioration of their physical condition and greater functional limitations may be the consequence of barring all future treatment. Commenter opines that functional improvement should be a goal in most cases, but unfortunately in these types of cases merely maintaining the current level of functional capacity will require continuing treatment. Commenter states that because the proposed language may serve to unfairly deny continued treatment to some of the most severely injured workers, she urges that proposed Section 9792.21(a)(2)(D) be amended to provide that additional treatment may be provided where medically necessary to cure or relieve from the effects of the injury or illness.		functional limitations or to maintain current functional capacity. The functional improvement definition as applicable in the proposed regulations is not meant to interfere with appropriate medical treatment. For example, in cases where acupuncture leads to functional improvement, and when the removal of acupuncture leads to functional decline, it is clear from the regulations that the appropriate treatment approach is to continue acupuncture. The requirement that acupuncture achieve functional improvement serves to appropriately justify continued acupuncture treatment as this would lead to a clinically significant improvement in activities of daily living or a reduction in work restrictions, and a reduction in the dependency on continued medical treatment. (See also, Response to Bo Thoreen, Esq. December 22, 2006, above.)	
Section 9792.21(a)(2)(B)	Commenter recommends that new sub-part (viii) be added to Section 9792.21(a)(2)(B), "Head and Shoulder." Commenter states that this sub-part would include the use of acupuncture and electroacupuncture for the treatment of: Shoulder Complaints, including Strain and Trauma Headache Head Trauma – Trauma Brain Injury	Sandra Carey of Carey and Associates on behalf of the Council of Acupuncture And Oriental Medicine Associations December 22, 2006 Written Comment	**Disagree.** The Acupuncture Medical Treatment Guidelines have been written based the State of Colorado Acupuncture Guidelines. DWC indicated in the December 2006 Notice of Modification of Text of Proposed Regulations (Notice) and Response No. 14—Acupuncture Medical Treatment Guidelines, which has been added to the 45 day comments chart—that upon review	None.

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	Temporomandibular Dysfunction Facial and Myofacial Pain Commenter states that she understands that the Colorado Guidelines do not cover the shoulder, and the intent of DWC is to defer to the ACOEM Guidelines in this specific area. Commenter opines, however, that the ACOEM Guidelines are deficient in the use of Acupuncture and this deficiency thereby would necessitate the inclusion of "Head and Shoulder" in the Acupuncture Medical Treatment Guidelines for acupuncture medical treatment. In support of this inclusion, commenter submits that there is high level Quality of Evidence; i.e., multiple well-designed, randomized controlled trials, directly relevant to the recommendation, yielding a consistent pattern of findings. Commenter states that strong recommendations, based on an evaluation of available evidence and general agreement of an expert panel, that acupuncture and electroacupuncture treatment is effective, always acceptable, and indicated. Commenter further states that the appropriateness of acupuncture/electroacupuncture has been determined by an Advisory Council of expert acupuncturists, based upon general consensus and after review of multiple published researches. Commenter states that this includes research accepted by the National Institutes of Health and the National Guidelines Clearinghouse and will be made available to DWC upon request.		of Colorado's guidelines on acupuncture it was determined that these guidelines were more on point with the requirements of Labor Code section 5307.27. [Citations] Thus, the Acupuncture Medical Treatment Guideline were crafted based on the Colorado Acupuncture Guidelines, and taking into consideration ACOEM's APG Insights, wherein ACOEM reviewed the medical literature and updated its position on the reasonableness of acupuncture treatment as an optional intervention. We further indicated in the Notice and Response No. 14 that as reflected in the Acupuncture Medical Treatment Guidelines, DWC crafted the guidelines based on the Colorado Guidelines but did not adopt their guidelines in their entirety to avoid conflict with the presumption of correctness pursuant to Labor Code section 4604.5(a). We indicated that ACOEM remains the foundation for the MTUS, and any supplemental guidelines including the Acupuncture Medical Treatment Guidelines, must be fitted to ACOEM as it provides the medical treatment framework for the MTUS appropriate for those conditions covered by ACOEM. As reflected in Section 9792.21(a)(2), DWC specified in the regulations that the Acupuncture	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING COMMENTS 1ST 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			Medical Treatment Guidelines supersede the ACOEM Practice Guidelines chapters of Neck and Upper Back Complaints, Elbow Complaints, Forearm, Wrist, and Hand Complaints, Low Back Complaints, Knee Complaints, Ankle and Foot Complaints, and Pain, Suffering, and the Restoration of Function. DWC indicated that the Colorado Medical Guidelines were used to the extent that it supplemented ACOEM in the area of acupuncture. The chapter Shoulder Complaints was not included because the Colorado Guidelines did not specifically identify acupuncture as a treatment for shoulder conditions, and the ACOEM Practice Guidelines does discuss acupuncture in this chapter. In Chapter 9. Shoulder Complaints, page 204, the ACOEM Practice Guidelines state: "[s]ome small studies have supported using acupuncture, but referral is dependent on the availability of experienced providers with consistently good outcomes." Thus, acupuncture is an option for shoulder complaints in ACOEM. However, we agree that this merits further evaluation. That is why we indicated in the Notice and Response No. 14 that the Advisory Committee will provide recommendations to the Medical Director concerning further development of consistent	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING COMMENTS 1ST 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			Acupuncture Medical Treatment Guidelines as needed.	
Section 9792.21(a)(2)	Commenter requests that DWC include "shoulder complaints" as one of the chapters cited in Section 9792.21(a)(2)(B) and to remove the exception for such complaints. Commenter acknowledges DWC's statement in the Notice that shoulder complaints were not included in the Acupuncture Medical Treatment Guidelines because the Colorado Guidelines did not specifically identify acupuncture as a treatment for shoulder conditions. Commenter also acknowledges that the ACOEM Practice Guidelines do contain a discussion of acupuncture for shoulder complaints. Commenter opines, however, that the discussion of acupuncture for shoulder complaints in the ACOEM Practice Guidelines is limited, and requests that it be included in the Acupuncture Medical Treatment Guidelines of the MTUS.	Bill Mosca, LAc Executive Director California Oriental Medicine Association December 22, 2006 Written Comment	**Disagree.** See response to Sandra Carey of Carey and Associates on behalf of the Council of Acupuncture And Oriental Medicine Associations, dated December 22, 2006, above.	None.
Section 9792.21(a)(2)	Commenter requests that DWC include shoulder complaints under this section. Commenter opines that to do so will clear the way for utilization review companies, workers' compensation adjustors, injured workers' and providers to follow.	Ta Fang Chen, C.A. Board Director California Acupuncture Medical Association December 21, 2006 Written Comment	**Disagree.** See response to Sandra Carey of Carey and Associates on behalf of the Council of Acupuncture And Oriental Medicine Associations, dated December 22, 2006, above.	None.
Section 9792.21(a)(2)	Commenter states that the acupuncture guidelines should be rewritten to separate definitions from substantive regulatory language, to eliminate superfluous words from definitions, and to eliminate definitions of terms that are not used in the text.	Lachlan Taylor Commission on Health and Safety and Workers' Compensation December 22, 2006 Written Comment	**Disagree**. The comment does not address the proposed changes made to the regulations subject to the 15-day notice. Although referring to the noticed Acupuncture Medical Treatment Guidelines, commenter offers no suggestions regarding how the Medical Treatment Guidelines	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING COMMENTS 1ST 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	Commenter suggests that DWC review the effect of including the general ACOEM chapter 6, "Pain, Suffering, and the Restoration of Function," because, in commenter's opinion, this will potentially obviate the effort to confine acupuncture to the other enumerate chapters.		should be re-written to accomplish his suggestions. **Disagree.** The comment does not address the proposed changes made to the regulations subject to the 15-day notice. Although referring to the noticed Acupuncture Medical Treatment Guidelines, commenter offers no reasoning as to how including the ACOEM's Chapter 6 in the Acupuncture Treatment Guidelines will "potentially obviate the effort to confine acupuncture to the other enumerated chapters." Moreover, ACOEM's Chapter 6 has already been incorporated into the MTUS by virtue of the adoption of the ACOEM Practice Guidelines into the schedule.	None.
Section 9792.21(a)(2)(D)	Commenter states that DWC's response 14 (at p.5), discusses the changes made to this section and states the word "objective," but the regulation does not contain that reference. Commenter states that as treatment milestone, the need to ascertain objective functional improvement is critical. Commenter adds that "objective" connotes a measurable, tangible, quantifiable result; one on which additional treatment may be based. Commenter recommends that the section be amended to state acupuncture treatments may be extended if objective functional improvement is documented as defined in Section 9792.20(e).	Brenda Ramirez Claims and Medical Director Michael McClain General Counsel & Vice President Alex Swedlow Executive Vice President California Workers' Compensation Institute December 22, 2006 Written Comment	**Disagree.** The December 2006 Notice of Modification of Text of Proposed Regulations (Notice) and Response No. 14—Acupuncture Medical Treatment Guidelines, which has been added to the 45 day comments chart, contain a typographical error when the word "objective" was used before the term "functional improvement" in this section. It was not the intention of DWC to modify our definition of "functional improvement" with the adjective "objective." DWC believes that the definition of functional improvement is sufficiently clear and it is not necessary to include the	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING COMMENTS 1ST 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			modifying adjective of "objective." We believe that the addition of the modifier in Section 9792.21(a)(2)(D) would be confusing and dilute the original meaning of the term as defined in Section 9792.20(e).	
Section 9792.21(a)(2)	Commenter states that the Colorado Acupuncture Medical Treatment Guidelines may be indicated for both joint stiffness and paresthesia. Commenter further states that these indications have been eliminated from the proposed California regulations' definition of "Acupuncture" [Section 9791.21(a)(2)(A)(i)] without any explanation in the Summary of Proposed Changes. Commenter sees no reason for the exclusion of these indications and urges the DWC to include both joint stiffness and paresthesia in the proposed definition of acupuncture.	Bill Mosca, LAc Executive Director California Oriental Medicine Association December 22, 2006 Written Comment	**Disagree.** As reflected in the December 2006 Notice of Modification to Text of Proposed, Regulations (Notice), at p. 12, and Response No. 14—Acupuncture Medical Treatment Guidelines, at pp. 5-6, which is part of the 45-day comments chart, the Acupuncture Medical Treatment Guidelines, were crafted based on the Colorado guidelines. However, we indicated in the notice that DWC did not adopt the Colorado guidelines in their entirety to avoid conflict with the presumption pursuant to Labor Code section 4604.5(a). We stated that ACOEM remains the foundation for the MTUS, and any supplemental guidelines including the Acupuncture Medical Treatment Guidelines, must be fitted to ACOEM as it provides the framework for the MTUS appropriate for those conditions covered by the ACOEM Practice Guidelines. This approach avoids conflict and the negation of the presumption of correctness pursuant to Labor Code section 4604.5(a). As reflected in Section 9792.21(a)(2), we specified in the	None.

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			proposed regulations that the Acupuncture Medical Treatment Guidelines supersede the ACOEM Practice Guidelines chapters of Neck and Upper Back Complaints, Elbow Complaints, Forearm, Wrist, and Hand Complaints, Low Back Complaints, Knee Complaints, Ankle and Foot Complaints, and Pain, Suffering, and the Restoration of Function. The Colorado guidelines were used to the extent that it supplemented ACOEM in the area of acupuncture. For example, we specified that the Chapter Shoulder Complaints was not included because the Colorado Guidelines did not specifically identify acupuncture as a treatment for shoulder conditions, and ACOEM Practice Guidelines does discuss acupuncture in this chapter. (See ACOEM Practice Guidelines, at p. 204). Commenter is concerned that "joint stiffness and paresthesia" are not included in the definitions describing the utility of acupuncture set forth in Section 9792.21(a)(2). Commenter indicates that the Colorado guidelines provide for these indications. Because ACOEM remains the foundation for the MTUS as reflected in the proposed regulations, and any supplemental guidelines including the Acupuncture Medical Treatment Guidelines, must be fitted to	

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			ACOEM, which sets forth the framework for appropriate treatment, it is not necessary to include "joint stiffness and paresthesia," or other symptoms not listed by commenter because ACOEM addresses these symptoms in its various body parts specific chapters. For Example, the ACOEM Practice Guidelines references paresthesias on pages 232-233, and therefore covers concerns raised by commenter. Moreover, as the MTUS, including the Acupuncture Medical Treatment Guidelines continue to be evaluated, the Advisory Committee will provide recommendations to the Medical Director concerning further development of these guidelines.	
Section 9792.21(a)(2)(E)	Commenter applauds Subdivision 9792.21(a)(2)(E) setting forth a statement regarding the professional discretion in connection with precautions, limitations, contraindications or adverse events resulting from acupuncture or acupuncture with electrical stimulations.	Bill Mosca, LAc Executive Director California Oriental Medicine Association December 22, 2006 Written Comment	**Accept**.	None.
Section 9792.21(c)	Commenter states that in response to earlier comments, DWC agreed that under the proposed regulations, the claims administrators are not required "to prove a negative." DWC noted that decisions to approve, modify or deny treatment are controlled by the Utilization Review Standards regulations and that a reference to the UR regulations in Section 9792.21(c) would be sufficient to clarify this process.	Brenda Ramirez Claims and Medical Director Michael McClain General Counsel & Vice President Alex Swedlow Executive Vice President	**Disagree**. The comment does not address the proposed changes made to the regulations subject to the 15-day notice. Commenter's language restricts the statute. Labor Code section 4604.5(e) requires that the authorized treatment not addressed by the MTUS be "in accordance with other … guidelines…." Thus, the proposed language that the claims administrator may rely on "one"	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING COMMENTS 1ST 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	Commenter opines, however, that the mere reference to the UR standards only reiterates the ambiguity. Commenter states that Section 9792.8(a)(2) repeats the admonition that treatment shall not be denied on the sole basis that the condition or injury is not addressed by the Medical Treatment Utilization Schedule and that when the condition or injury is not addressed by the schedule, "treatment shall be in accordance with other evidence-based medical treatment guidelines that are generally recognized by the national medical community and are scientifically based." Commenter opines that as drafted, the proposed regulations are still unclear as to whether the claims administrator is required to support its treatment utilization review decision with another medical treatment guideline, or is required to prove that the requested treatment is not supported by <u>any other</u> medical treatment guideline or nationally recognized medical evidence. The proposed language may be read to mean that a request for treatment must be authorized if it is in accordance with a guideline with a low strength of evidence, even if this contradicts another guideline with a high strength of evidence. Commenter states that the goal of the statute is to provide the injured employee with high-quality, effective medical care. Commenter urges a further clarification to reflect DWC's intention that when a condition is not addressed by the treatment schedule, the claims administrator must support its decision	California Workers' Compensation Institute December 22, 2006 Written Comment	guideline restricts the statute. In our previous response to Commenter's comment on the very same issue, DWC stated that the MTUS regulations do not change the current Utilization Review practice. We agreed that the insurer is not required "to prove a negative." Decisions to approve, modify or deny treatment continue to be controlled by the Utilization Review Standards regulations (Section 9792.6 through Section 9792.10). Pursuant to commenter's previous comments Section 9792.21(c) was clarified by adding a reference to the Utilization Review regulations. DWC previously disagreed with commenter's proposed language as not necessary. Section 9792.21(c) is clear that there will be situations where the MTUS will not address certain conditions or injuries. In those situations, the claims administrator is responsible to provide treatment pursuant to other treatment guidelines that meet the requirements of that section. If examined guidelines do not support the treatment request, the claims administrator may request "appropriate information which is necessary to render a decision" following UR process and appropriate timeline. (See, CCR, Section 9792.9.) This would include requesting from the requesting physician "specific references to and	

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	with one or more evidence-based, nationally recognized, peer-reviewed medical treatment guidelines. Commenter opines that the recommended revisions will clarify the obligations of the utilization reviewer and the physician requesting the treatment, and will ensure a higher standard of care for the injured employee. Pursuant to her explanation, commenter recommends that Section 9792.21(c) be amended as follows: Treatment shall not be denied on the sole basis that the condition or injury is not addressed by the Medical Treatment Utilization Schedule. ~~In this situation, the claims administrator shall authorize treatment if such treatment is~~ Authorization decisions to approve, modify or deny treatment for a condition or injury not addressed by the Medical Treatment Utilization Schedule shall be made in accordance with ~~other~~ one or more other scientifically and evidence-based medical treatment guidelines, if any, that address the condition or injury, and that are nationally recognized by the medical community, in accordance with subdivisions (b) and (c) of section 9792.22, and pursuant to the Utilization Review Standards found in Section 9792.6 through 9792.10. When a requesting physician disagrees with the modification or denial of a request for authorization, the physician may submit for consideration, together with the request, specific references to and excerpts from other		excerpts from other nationally recognized, scientifically and evidence-based medical treatment guidelines" or other MEDLINE references. The claims administrator does not need to conduct a MEDLINE search to "prove a negative" i.e., that the request for treatment is not supported by the medical literature.	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING COMMENTS 1ST 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	nationally recognized, scientifically and evidence-based medical treatment guidelines.			
Section 9792.21(c)	Commenter states that the proposed language of section 9792.21(c) is contradicted in Section 9792.22(c)(1). Commenter indicates that Section 9792.22(c)(1) addresses conditions or injuries not addressed by either subdivisions (a) or (b) [of Section 9792.22]. Commenter further indicates that Section 9792.22(c)(1) establishes Section 9792.22(b) as a stand-alone criteria. Commenter then adds that the language proposed in 9792.21(c) links sections 9792.22(b) and 9792.22(c) together as a single requirement. Commenter requests that the Division omit the words "subdivisions (b) and (c) of" in this section.	Mary Ann Clark, MHA Director, Health Economics and Reimbursement Advanced Bionics December 22, 2006 Written Comment	**Disagree.** We find no conflict in the referenced sections set forth by commenter. See response to Brenda Ramirez, December 22, 2006, clarifying the applicability of these sections, above.	None.
Section 9792.21(c)	Commenter states that there appears to be tension between the MTUS (which adopts the ACOEM Practice Guidelines) which is presumptively correct and the requirement that the MTUS will not serve as the sole basis to deny treatment. Commenter states that in section 9792.21(c), the proposed section states that "treatment shall not be denied on the sole basis that the condition or injury is not addressed by the Medical Treatment Utilization Schedule". However, section 9292.22 states that "The Medical Treatment Utilization Schedule is presumptively correct…." Commenter opines that practically treatment will be denied based on its not being addressed in the MTUS. Commenter further adds that this would seemingly be the effect of presuming the MTUS to be correct--treatment will be denied. Commenter states that it will then fall to the physician to make a case to rebut the presumption. Commenter opines that	Bo Thoreen, Esq. December 22, 2006 Written Comment	**Disagree.** The proposed regulations are drafted to reflect that the MTUS is presumed to be correct pursuant to the statute. (Lab. Code, § 4604.5(c).) However, the statute further requires that if the condition or injury is not addressed in the MTUS, treatment must be authorized based on other guidelines that meet the requirements of the statute. (Lab. Code, § 4604.5(e). Therefore, while the presumption will be applicable to the MTUS if the condition or injury is addressed, the presumption will not apply to the MTUS, if the condition or injury is not addressed and the treating physician relies on other guidelines to request treatment. Moreover, if the condition or injury is addressed by the MTUS, the presumption of correctness may be	None.

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	this tension should be resolved.		overcome pursuant to Section 9792.22(a) as required by Labor Code section 4604.5(a).	
Section 9792.21(c) and 9792.22(b)	Commenter requests that the Division strike the addition of the word "nationally" before "recognized by the medical. . . ." in both of these sections. Commenter believes that the addition of the word "nationally" significantly modifies both of these sections. Commenter further believes that the intent would be to require a claims administrator to authorize treatment if the treatment is in accordance with evidence based guidelines recognized by the medical community. Commenter references the definition of the term "evidence-based" (a systematic review of literature published in medical journals included in MEDLINE). Commenter also references a portion of the definition of the term "MEDLINE" (the largest component of PubMed). Commenter then extrapolates that by adding the word "nationally" the DWC is modifying the intent and creating a conflict in the regulations. Commenter believes that DWC needs to recognize that some U.S. state government's standards could be in direct conflict with the evidence based guidelines. Commenter offers the example of the State of Colorado's Division of Workers' Compensation, Executive Summary of the Medical Treatment Guideline Case Review and Cost Study, General introduction, page 1, which states regarding its guideline development: "Medical treatment guidelines were developed through consensus incorporating community input." Commenter	Kelly M. Weigand, Esq. First Health December 20, 2006 Written Comment	**Disagree**. Commenter states that she believes that the intent of the regulations is to require a claims administrator to authorize treatment if the treatment is in accordance with evidence-based guidelines recognized by the medical community. Commenter opines that by adding the word "nationally," the DWC is modifying the intent and creating a conflict in the regulations. The modifications in these two sections were explained in Response No. 5—"Generally recognized by the national medical community" language and definition of the term "nationally recognized," which is part of the 45-day chart, and states in pertinent part as follows: *Labor Code section 77.5 required the Commission on Health and Safety and Workers' Compensation (CHSWC) to "conduct a survey and evaluation of evidence-based, peer-reviewed, nationally recognized standards of care, including existing medical treatment utilization standards, including independent medical review, as used in other states, at the national level, and in other medical benefit systems," and*	None.

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	states that the guidelines adopted by Colorado do not appear to be evidence-based.		*to "report … its findings and recommendations to the administrative director for purposes of the adoption of a medical treatment utilization schedule." (Emphasis added.)* *Labor Code section 5307.27 requires, in relevant part, the "administrative director … [to] adopt … a medical treatment utilization schedule that shall incorporate the evidence-based, peer-reviewed, nationally recognized standards of care …." (Emphasis added.)* *Labor Code section 4604.5(b) requires, in pertinent part, that "[t]he recommended guidelines set forth in the schedule adopted … shall reflect practices that are evidence and scientifically based, nationally recognized, and peer-reviewed." (Emphasis added.)* *Labor Code section 4604.5(e) provides, on the other hand, that for "all injuries not covered by the … official utilization schedule after adoption …, authorized treatment shall be in accordance with other evidence based medical treatment guidelines generally recognized by the national medical community and that are scientifically based. (Emphasis added.)*	

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			While Labor Code sections 77.5, 5307.27 and 4604.5(b) consistently refer to "nationally recognized" by the medical community when referring to medical treatment guidelines, section 4604.5(e) uses the term "generally recognized by the national medical community." After review of the Labor Code sections as set forth above, the Administrative Director determines that both terms have essentially the same meaning, and in order to implement, interpret, and make specific Labor Code section 4604.5(e), it is necessary to harmonize this section with the remaining statutes (Lab. Code, §§ 77.5, 5307.27, and 4604.5(b).) In this regard, the Administrative Director determines that it is appropriate to use the term "nationally recognized" throughout the regulations as this term is used consistently in Labor Code sections 77.5, 5307.27 and 4604.5(b), and it is already defined in the proposed regulations. Accordingly, the language "generally recognized by the national medical community" contained in sections 9792.21(c) and 9792.22(b) will be substituted with the language "nationally recognized." Commenter is incorrect that by adding the word "nationally" DWC	

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			is modifying the intent of the regulations and creating a conflict in the regulations. To the contrary, as explained in Response No. 5, the addition of the word "nationally" to Sections 9792.21(c), and 9792.22(b), the DWC harmonized the statutes as explained above. The statutes' requirement is clear that when using other guidelines outside of the MTUS to support a medical treatment decision the guideline must be evidence and scientifically based, nationally recognized and peer reviewed. Commenter argues that some U.S. state government's standards could be in direct conflict with the evidence based guidelines. Commenter argues that the Colorado Guidelines are not evidence-based because they were developed through consensus. In support of her comment, commenter cites a document of the State of Colorado's Division of Workers' Compensation, entitled: *Executive Summary of the Medical Treatment Guideline Case Review and Cost Study*. Commenter references the general introduction of that document at page 1, which states regarding its guideline development: "Medical treatment guidelines were developed through consensus incorporating community input". Commenter believes that the referenced	

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			document supports her opinion that the guidelines adopted by Colorado are not evidence-based. We disagree. DWC reviewed the document referenced by commenter which is located at: http://www.coworkforce.com/dwc/PUBS/execsummary.pdf. This document sets forth a cost analysis for treatments of common conditions in workers' compensation. However, the document does not pertain directly to the guidelines development process. A review of the Colorado Medical Treatment Guidelines reflects that the Colorado Guidelines incorporated an evidence-based approach. For example, Exhibit 1 on Low Back Pain, page 3, states that guideline recommendations are based on available evidence and/or consensus recommendations. It further states that when possible, guideline recommendations will note the level of evidence supporting the treatment recommendation. See Colorado's Back Guideline at http://www.coworkforce.com/dwc/Rules/Rules2005/Final%20Exh.%201%20%20Low%20Back%20Pain.pdf Moreover, the *State of Colorado, Division of Workers' Compensation, Medical Treatment Guidelines-Evidence-Based Parameters*, reflects that the Colorado guidelines are	

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			evidence-based. This document sets forth the derivation of evidence-based recommendations by a process of systematic literature review and graded recommendations. If the systematic literature review fails to provide adequate scientific studies or reveals conflicting studies, then multidisciplinary consensus judgment is applied. (See, *State of Colorado, Division of Workers' Compensation, Medical Treatment Guidelines—Consensus Parameters*.)	
Section 9792.22(b)	Commenter states that the change in Section 9792.22(b) clarifies that medical treatment and authorization decisions may be based on one or more guidelines recognized by the national medical community. Commenter recommends that Section 9792.22(b) be further amended as follows: "For all conditions or injuries not addressed by the Medical Treatment Utilization Schedule, authorized treatment and diagnostic services shall be in accordance with <u>one or more</u> other scientifically and evidence-based medical treatment guidelines that are nationally recognized by the national medical community."	Brenda Ramirez Claims and Medical Director Michael McClain General Counsel & Vice President Alex Swedlow Executive Vice President California Workers' Compensation Institute December 22, 2006 Written Comment	**Disagree.** Commenter's language restricts the statute. Labor Code section 4604.5(e) requires that the authorized treatment not addressed by the MTUS be "in accordance with other … guidelines…." Thus, the proposed language that the claims administrator may rely on "one" guideline restricts the statute.	None.
Section 9792.22(b)	Commenter requests that DWC avoid circular logic of a section of the MTUS purporting to address situations that are "not addressed by the MTUS." Commenter further states that the internal cross references have to be thoroughly mapped out. Commenter adds that definitions should not include substantive text or operational language (language which	Lachlan Taylor Commission on Health and Safety and Workers' Compensation December 22, 2006 Written Comment	**Disagree.** The comment does not address the proposed changes made to the regulations subject to the 15-day notice.	None.

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	enacts law by regulatory fiat), and therefore the incorporation by reference does not belong. Without further explanation, commenter quotes verbatim Labor Code section 4604.5.			
Section 9792.22(c)(1)	Commenter states that he is encouraged by the proposed adoption of ACOEM's "strength of evidence rating methodology" as the means to determine allowable treatment. Commenter believes this framework can serve to guide the work of the Medical Evidence Evaluation Advisory Committee, which will be charged with considering any changes or additions to the presumptive standard, the ACOEM Practice Guidelines, 2nd Edition.	Steven C. Schumann, MD Legislative Chair Western Occupational & Environmental Medical Association (WOEMA) December 22, 2006 Written Comment	**Accept**.	None.
Section 9792.22(c)(1)	Commenter states that this paragraph proposes a new "strength of evidence" methodology to be used to evaluate medical evidence used to rebut a presumptively correct guideline or to justify a treatment that is not addressed by these guidelines. Commenter recognizes that this methodology was utilized by ACOEM in the development of its guidelines. Commenter strongly urges that this complex and confusing process not be adopted as the methodology to rank the strength of any evidence that may be submitted in individual cases. Commenter opines that the adoption of this methodology would create enormous problems for all system participants.	Linda F. Atcherley President California Applicants' Attorneys Association December 22, 2006 Written Comment	**Disagree.** Labor Code section 5307.27 requires that the acting Administrative Director adopt a medical treatment utilization schedule that is, among other things, "evidence-based." Moreover, Labor Code section 4604.5(b) states, in relevant part, that the schedule adopted "shall reflect practices that are evidence and scientifically based …." Evidence-based medicine is a relatively new field, and continues to evolve as new standards are being adopted to systematically review the scientific evidence. In this regard, ACOEM has revised its methodology to classify the evidence to comply with internationally recognized standards. ACOEM is among many organizations who are adopting similar standards in systematic review of the scientific evidence.	None.

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			Commenter opines that ACOEM's methodology is a "complex and confusing process." To the contrary, not having a Strength of Evidence Methodology would be more complex and confusing. The proposed regulations set forth the process for applying the ACOEM's Strength of Evidence as follows. Use of the Strength of Evidence Methodology can be used to support treatment under Section 9792.22(c) when the physician is proposing treatment of condition which treatment (1) is not addressed by the MTUS or other guidelines, (2) is at variance with the MTUS and/or other guidelines, or (3) is addressed in two guidelines or more, and the physician prefers to use one guidelines over the other guideline. The first step in applying the Strength of Evidence Methodology, is to start examining the 11 criteria set forth in Section 9792.22(c)(1)(A)—Criteria Used to Rate Randomized Controlled Trials (Table A). Table A provides at the very top preceding this table that the studies are rated using a scoring system based in applying 11 criteria. The Section further indicates that each criterion is rated 0, 0.5, or 1.0, thus the overall ratings range from as score of 0 to a maximum of 11. It	

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			further indicates that a study is considered low quality if the composite rating was 3.5 or less, intermediate quality if rated 4-7.5, and high quality if rated 8-11. A score of 3.5 means that the medical article is at least "intermediate quality" pursuant to the paragraph preceding Table A. After obtaining a composite rating, the next step is to apply Section 9792.22(c)(1)(B)—Strength of Evidence Ratings (Table B). Table B provides for the Strength of Evidence Rating. Continuing with the analysis presented above, the physician presenting a medical article of at least "intermediate quality" would use Table B to determine the strength of evidence, which in this case would be level "C". This approach is not as "complex and confusing" to medical specialists who are scientifically trained to practice in their fields of expertise, and would most appropriately be one requesting the medical treatment. **We disagree** with the comment that the adoption of this methodology would create enormous problems for all system participants. ACOEM's methodology is based on internationally recognized and scientifically valid methods to rank the strength of evidence for the	

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			development of practice guidelines. ACOEM is adapting, for occupational medicine, a system that is commonly used worldwide (i.e., Cochrane Collaboration) in one form or another. One of ACOEM's goals, as reflected in its guideline, is consistency (particularly important if providers are evidence-driven specialists), so that something applied in workers' compensation conforms to evidence-based medicine unless there is a very good reason not to follow this approach, such as new evidence. ACOEM's methodology, as adopted in the proposed regulations under Section 9792.22(c)(1), is appropriate and consistent with the requirements of the statute. (See, Lab. Code, §§ 5307.27, 4604.5(b).)	
Section 9792.22(c)(1)	Commenter states that ACOEM may have both the expertise and personnel to undertake the complicated analysis necessary to assign a strength ranking to each and every study that is evaluated in the adoption of its guidelines. Commenter opines, however, that it is completely unrealistic to believe that individual injured workers or employers, the treating physician, or even a Qualified Medical Examiner or Agreed Medical Examiner, is going to be able to develop the correct strength ranking for each new evidence-based study published in the medical literature.		**Disagree.** As previously indicated there is no need for any of the aforementioned individuals to compile their own strength-of-evidence rating unless they wish to support treatment which is at variance with MTUS, other guidelines, or not addressed in any guideline. Moreover, the injured worker and the employer, if a dispute arises, would be, of course, relying on the expertise of their physicians, and would be presenting evidence obtained from those specialists in support of their respective positions.	None.

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			For approach to use of the Strength of Evidence and further response on the subject, see response to comment submitted by Linda F. Atcherley, dated, December 22, 2006, at the top of this section.	
Section 9792.22(c)(1)	Commenter opines that as a consequence, injured workers may be denied the most efficacious treatment simply because the physician could not work through this methodology to assign a strength ranking.		**Disagree**. To the contrary, this methodology will insure that the injured worker will receive the "most efficacious treatment" because the treatment recommendation is based on scientific evidence. This scientific evidence is derived from a process wherein all high quality studies for a particular topic are identified, screened, and rated and the results of the rating summarized. This summary of the strength of evidence becomes the core of the recommendation for clinical practice. For approach to use of the Strength of Evidence and further response on the subject, see response to comment submitted by Linda F. Atcherley, dated, December 22, 2006, at the top of this section.	None.
	Commenter questions what are the Workers' Compensation Administrative Law Judges (WCJ) to do when presented with evidence that, on its face, appears to justify a different treatment than called for in the guidelines? Commenter further questions whether WCJs will be forced to wade through this complicated methodology themselves, or will they simply reject any treatment option – even		**Disagree.** The proposed regulations and the statute provide for a presumption of correctness attributable to the medical treatment utilization schedule (MTUS). (Lab. Code, §4604.5(a), Proposed Section 9792.22(a).) The statute, as well as the proposed regulations, also provides that the presumption is	None.

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	one that otherwise appears appropriate – simply because the physician could not and did not calculate the ranking?		rebuttable and may be controverted by a preponderance of scientific medical evidence. (Lab. Code, §4604.5(a), Proposed Section 9792.22(a).) If a Workers' Compensation Administrative Law Judge (WCJ) is presented with evidence that, on its face, appears to justify a different treatment than other set forth in the MTUS, the WCJ is required to determine whether the presumption has been rebutted by a preponderance of the scientific evidence, that is whether the proposing party has met the burden of proof to overcome the presumption. (Lab. Code, § 4604.5(a).) It would appear that in this regard, the parties would submit evidence justifying their positions. This would entail, for example, evidence showing that the proposed treatment recommendation is based on scientific evidence. This evidence may consist of guidelines that support the treatment which meet the requirements of the statute. (Lab. Code, § 4604.5(e), Proposed Section 9792.22.(b).) It may also entail use of the Strength of Evidence Methodology under Section 9792.22(c) if the physician is proposing treatment of condition which treatment (1) is not addressed by the MTUS or other guidelines, (2) is at variance with the MTUS and/or other guidelines, or (3) is addressed	

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			in two guidelines or more, and the physician prefers to use one guideline over the other guideline. The WCJ would then be weighing the evidence in issuing his or her decision to determine whether the burden of proof has been met. (Lab. Code, § 3202.5) For approach to use of the Strength of Evidence and further response on the subject, see response to comment submitted by Linda F. Atcherley, dated, December 22, 2006, at the top of this section.	
Section 9792.22(c)(1)	Commenter suggests that instead of adopting this complex process for ranking strength of evidence, a simplified process be adopted similar to the ranking methodology used by AAOS, as cited on page 27 of the ISOR, as follows: Type I Meta-analysis of multiple, well-designed controlled studies; or high-power randomized, controlled clinical trial. Type II Well-designed experimental study; or low-power randomized, controlled clinical trial. Type III Well-designed, non-experimental studies such as nonrandomized controlled single-group, pre-post, cohort, time, or matched case-control series. Type IV Well-designed, non-experimental studies, such as comparative and correlational descriptive and case studies. Type V Case report and clinical examples. Commenter believes that adoption of a strength ranking methodology similar to		**Disagree.** The ACOEM Practice Guidelines is the foundation for the MTUS and it is more appropriate to use ACOEM's Strength of Evidence in the framework for the MTUS appropriate for those conditions covered by the schedule. This approach avoids conflict and the negation of the presumption of correctness pursuant to Labor Code section 4604.5(a). Moreover, ACOEM's methodology is based on internationally recognized and scientifically valid methods to rank the strength of evidence for the development of practice guidelines. ACOEM is adapting, for occupational medicine, a system that is commonly used worldwide (i.e., Cochrane Collaboration) in one form or another. However, it is noted that the ranking used by AAOS is similar to that used by ACOEM and	None.

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	AAOS will allow physicians and other system participants to assign a proper strength ranking to new studies and reports. Commenter opines that this will insure that the most current medical evidence is utilized in reviewing the appropriateness and necessity of requested medical treatments that are not covered by or are in conflict with the published treatment guidelines.		Cochrane. The ACOEM method is not complex; rather it is designed to be transparent and reproducible. Note that AAOS, similar to ACOEM and others are classification systems which describe the strength-of-a-study design. They are not the basis for the critical analysis of each study or the basis for determining the strength of the body of evidence. Of great importance is that these methods all recognize that there is a hierarchy of study design based on reproducibility of results (and consequently likely clinically significant benefit). This means that higher quality evidence trumps lower quality evidence in assessing the probability that the test or treatment will reliably accomplish its intended benefit. It also means that relying on lower quality evidence of necessity markedly increases the probability that the intervention will eventually be found to be either ineffective or even harmful. The difference between these two methods is that ACOEM's method creates more categories within the top two AAOS rankings to better delineate these differences. These changes were incorporated to provide even greater clarity. AAOS, as well as other professional organizations, participated in reviewing and revising the ACOEM methodology	

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Section 9792.22(c)(1)	Commenter further opines that use of AAOS ranking methodology will not only lower administrative costs, as conflicts over rankings will be minimized, but should minimize both treatment and indemnity costs as workers recover faster and return to work more quickly.		and are well represented in the processes of updating the Guidelines. These representatives from other professional organizations are included in this process because ACOEM recognizes and values the contributions of a multi-disciplinary team. Because the ACOEM Practice Guidelines have been adopted as part of the MTUS, it is most logical to use their methodology to insure internal consistency within the schedule. **Disagree.** Because these two methodology systems are very similar there is no great difference in administrative costs. Moreover, it is believed that an evidence-based approach of relying on the highest quality evidence, regardless of the ranking methodology used, will result in patients receiving the best quality care possible which would also reduce net workers' compensation system costs as they recover faster, which is indeed the goal of the reform legislation.	None.
Section 9792.22(c)(1)	Commenter opines that modifications to this section suffer from a lack of clarity and necessity as those terms are defined in the Administrative Procedure Act.	Anthony J. DeCristoforo, Esq. – Wilke, Fleury, Hoffelt, Gould & Birney, LLP on behalf of Empi, Inc. December 22, 2006 Written Comments	**Agree in part. Disagree** with the comment that the modifications to Section 9792.22(c)(1) do not comply with the "necessity" standard of Government Code section 11349.1. The California Code of Regulations, Title 1, section 10, states, in relevant part, that in order to meet the "necessity standard" of Government Code section 11349.1, the	None.

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			rulemaking file shall include: "(1) A statement of the specific purpose of each adoption ….; and (2) information explaining why each provision of the adopted regulation is required to carry out the described purpose of the provision…." The Initial Statement of Reasons, at pp. 43-45 sets forth the purpose and necessity of adopting a "hierarchy of scientific based evidence." (See also, Notice of Proposed Rulemaking, dated July 2006, at pp. 5-6.) Thereafter, the Notice of Modification to Text of Proposed Regulations issued in December 2006, clearly explained at pp. 15-20, the modification to Section 9792.22(c)(1). The December 2006 15-day Notice specifically stated at p. 19, that during the 45-day comment period, ACOEM notified DWC that it would adopt a new methodology to evaluate the scientific evidence for its updates of the ACOEM Practice Guidelines, 2nd Edition. We further indicated in the December 2006 15-day Notice, at p. 20, that because ACOEM updated its methodology, and in light of the fact that DWC proposes to adopt ACOEM into the MTUS, Section 9792.22(c)(1) was amended to reflect ACOEM's updated methodology. We further stated that ACOEM remains the foundation for the MTUS, and the adoption of the updated methodology	

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			allows the MTUS to remain consistent with ACOEM's current methodology to evaluate evidence-based medical treatment guidelines. An explanation from ACOEM of the new methodology was set forth in the December 2006 15-day Notice, at pp. 19-20. Furthermore, although commenter states that the modifications to this section suffer from a lack of necessity as the term is defined in the Administrative Procedures Act, commenter offers no argument in support of his comment. DWC **agrees**, however, that further clarification of Section 9792.22(c)(1)(A) is necessary in order to ensure that it is readily understandable to the persons directly affected by the proposed regulations as required by Government Code section 11349.1. (See, California Code of Regulations, Title 1, section 16.) Changes to this section will be explained below in connection with commenter's specific comments.	
Section 9792.22(c)(1)	Commenter states that the Randomization section of Table A includes several references to "successful" randomization. Commenter states that the term "successful" is vague and subjective, and should either be removed, or at the very least be defined. Commenter states that the use of such an ambiguous term subjects the regulations to the criticism that		**Agree.** DWC agrees with the comment that an explanation of the context in which the term successful is used is necessary to clarify Section 9792.22(c)(1)(A). Successful randomization is a statistical concept. It entails, as stated in *Evidence-based Medicine: How to Practice and*	**Section 9792.22(c)(1)(A)** setting forth Table A – Criteria Used to Rate Randomized Controlled Trials has been amended under the "Randomization" criteria to include an explanation

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	they cannot be easily understood by those persons directly affected by them. Commenter adds that any attempt to define the term "successful" would require an opportunity for the public to comment on the definition. Commenter states that when achieved, true randomization can only be measured as successful by allocating the desired number of patients to each treatment group. Commenter states that it does not ensure equivalence of all variables across groups. Commenter states that any attempt to qualify the success of randomization based on outcomes of participant variables is invalid.		*Teach EBM* (2005), at p. 118, "Randomization balances the treatment groups for prognostic factors, even if we don't yet know enough about the target disorder to know what they all are. If these factors exaggerated the apparent effects of an otherwise ineffectual treatment, the effects of their imbalance could lead to the false-positive conclusion that the treatment was useful when in fact it wasn't. In contrast, if they nullified or counteracted the effects of a really efficacious treatment, this could lead to a false-negative conclusion that a useful treatment was useless or even harmful. We should insist on random allocation to treatment because it comes closer than any other research design to creating groups of patients at the start of the trial who are identical in their risk of the event we are trying to prevent. We determine if the investigators used some method analogous to tossing a coin to assign patients to treatment groups." After discussions with ACOEM, ACOEM has agreed that it is necessary for clarification purposes to add an explanation of the context in which the term successful is used in Table A. Commenter is correct that simply allocating individuals to groups does not constitute sufficient grounds to assess the success of randomization. In order to assess the	of the context in which the term successful is used. The explanation states: "Simply allocating individuals to groups does not constitute sufficient grounds to assess the success of randomization. The groups must be comparable; otherwise, the randomization was unsuccessful".

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			success of randomization, the additional factor is that the groups must be comparable, otherwise the randomization was unsuccessful. Unsuccessful randomization can also be addressed by statistically controlling for variables known to be associated with the outcome measure under investigation in any analysis. Pursuant to a document submitted by ACOEM entitled *Amendments to ACOEM's Methodology Advances for Occupational Practice Guidelines, 2nd Edition*, dated March 13, 2007, which has been added to the rulemaking file, **Subdivision (c)(1)(A)** setting forth Table A – Criteria Used to Rate Randomized Controlled Trials has been amended. Table A, under the "Randomization" criteria has been amended to include an explanation of the context in which the term successful is used. The explanation states: "*Simply allocating individuals to groups does not constitute sufficient grounds to assess the success of randomization. The groups must be comparable; otherwise, the randomization was unsuccessful"*. Moreover, it is noted that in no way does ACOEM incorporate outcomes in the assessment of the success of randomization.	
Section 9792.22(c)(1)	Commenter adds that all of this calls into question whether the totality of the record has		**Disagree**. It is not clear what commenter means when he states	None.

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	been taken into account in the promulgation of the modification to the proposed regulations.		that "this calls into question whether the totality of the record has been taken into account in the promulgation of the modification to the proposed regulations." This regulation is undergoing formal rulemaking, proper notice has been served on the public, a hearing has been conducted, and proper notices for 15-day changes have issued. The comments of the public during this process have been taken into consideration in the various modifications to the regulations, and the responses to the comments have been made public. If comment refers to the ACOEM methodology, it is noted that the methodology takes into account the totality of the quality medical and scientific evidence to support the efficacy of a treatment (or test), and performs a quality assessment rating on every study meeting inclusion criteria. The entire process is clear, concise, and highly transparent as noted above**.**	
Section 9792.22(c)(1)	Commenter states that the Baseline Comparability section of Table A has a similar problem in that randomization is done in the absence of consideration of these factors. Commenter indicates that while randomization is intended to minimize such differences between treatment groups, it cannot guarantee success.		**Agree in part.** DWC agrees that there is never a guarantee that randomization is successful. However, baseline comparability must be assessed post hoc to ensure that randomization has accomplished its desired effect. Randomized controlled clinical trials are performed and are unequivocally	None.

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			considered the best study design to address questions about the efficacy, or comparability, of various treatments.	None.
Section 9792.22(c)(1)	Commenter adds that if there are significant differences between groups at baseline, specific statistical measures (e.g., covariate analysis) can be employed to determine whether these differences have any meaningful impact on the results. Commenter states that following best practices in no way ensures baseline comparability, but is the best method to approach comparability.		**Agree.** DWC understands this comment to mean that even if best practices for assigning individuals to groups are followed, namely through randomization, this does not insure that groups are comparable at baseline. If there are significant differences between groups at baseline, then the randomization, even if well carried out, was not successful. DWC further understands that one way to address any lack of comparability between groups at baseline despite following best practices is to statistically adjust or control for baseline variables in any outcome analysis.	
Section 9792.22(c)(1)	Commenter states that the Co-interventions Avoided section of Table A is problematic. Commenter opines that while co-interventions can mask significant effects or make non-significant effects appear significant, they can be controlled much more practically than they can be avoided. Commenter adds that any therapy that is adjunctive, by necessity, requires a co-intervention. Commenter concludes that as such, this criterion should be changed to reflect how any co-interventions were controlled rather than how they were avoided.		DWC agrees that co-interventions are problematic, especially in musculoskeletal studies where they are common. Yet, the strength of the ACOEM methodology is that it recognizes the problem and does not exclude articles with such co-interventions, but rather incorporates this issue into the article rating. It is not possible to control for co-interventions in all circumstances, and in many studies they are tracked poorly such that an independent analysis of this problem is not	**Section 9792.22(c)(1)(A)** setting forth Table A – Criteria Used to Rate Randomized Controlled Trials has been amended. The Co-interventions section of the Table has been amended to reflect how co-interventions were controlled for rather than avoided. The Section now states: "**Controlled for Co-interventions:** The degree to which the study design controlled

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			possible. However, because there may be flaws, ACOEM has determined that it is better to include a rating criterion that accounts for co-intervention, rather than excluding studies that did not control for them. ACOEM has agreed that the criterion should reflect how co-interventions were controlled for rather than avoided, and has incorporated this change into its revised Table A. (See, Amendments to ACOEM's Methodology Advances for Occupational Practice Guidelines, 2nd Edition, March 13, 2007, which has been added to the rulemaking file.)	for multiple interventions (e.g., a combination of stretching exercises and anti-inflammatory medication or mention of not using other treatments during the study)."
Section 9792.22(c)(1)	Commenter states that the Analyzed by Intention to Treat criterion should be completely removed. Commenter further states that while intention to treat (ITT) analysis can be useful and does have a place in clinical research, it is far from a form of analysis that is applicable to all forms of clinical trials. Commenter indicates that analysis of studies using a per protocol design are important to determine how well an intervention works (i.e., the maximum effectiveness), whereas ITT analyses may be more accurate to determine the pragmatic effect of a given intervention. Commenter indicates that in effect, the two forms of analysis seek to answer different questions and depending on the question being asked, each has its own time and place. Commenter opines that the decision whether to use ITT analysis or per protocol analysis must be made during the study design, and not employed		**Disagree.** Intention-to-treat analysis is the standard criterion in most evidence-based medicine processes, including the Cochrane Collaboration and the Oxford and McMaster groups. Intention–to-treat analysis is used "to preserve randomization" (See, *Evidence-based Medicine: How to Practice and Teach EBM* (2005), 3rd Edition, Strauss, Richardson, Glasziou, and Haynes, at p. 281.)	None.

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	after data collection. Commenter concludes that it is therefore inappropriate to assign one type of analysis greater weight in determining the quality of a given trial.			
Section 9792.22(c)(1)	Commenter opines that one of the critical issues facing the DWC was the fundamental conflict between the ACOEM ***Guidelines*** and Labor Code Section 5307.27. Commenter states that all treatment guidelines are mandated by statute to be evidence-based. Commenter indicates that the ACOEM ***Guidelines***, however, were proven through an analysis provided to the DWC by CSIMS to be based, in the majority, on consensus. Commenter states that the DWC's original proposal omitted consensus as a valid level of evidence.	Steven J. Cattolica Carlyle Brakensiek Advocal December 22, 2006 Written Comment	**Disagree.** DWC does not agree with the comment that there is a fundamental conflict between the ACOEM Guidelines and Labor Code Section 5307.27. The ACOEM Practice Guidelines are evidence-based and comply with the requirements of the statute. Commenter's previous comment on the issue of consensus was addressed in the 45-day Comments chart at pp. 58-59. In its response DWC stated: "The ACOEM Practice Guidelines are evidence-based as it uses a systematic review of the literature published in journals as its basis."	None.
Section 9792.22(c)(1)	Commenter states that ACOEM acknowledged the validity of this issue and responded by changing its method of evaluating evidence and the terminology used to describe it. Commenter states that they did so by eliminating the phrase "consensus." (Commenter references Page 14 of 22 and the following pages describing changes to Section 9792.22 of the Adobe Acrobat formatted document titled, "Notice of Modifications to Text.")		**Disagree** with commenter's comment that ACOEM acknowledged the validity of this issue and responded by changing its method of evaluating evidence and the terminology used to describe it. As previously stated, evidence-based medicine is a relatively new field, and continues to evolve as new standards are being adopted to systematically review the scientific evidence. In this regard, ACOEM has revised its methodology to classify the evidence to comply with internationally recognized standards.	None.

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			ACOEM is among many organizations who are adopting similar standards in systematic review of the scientific evidence. (For further discussion of this issue, see December 2006 Notice of Modification to Text of Proposed Regulations, at pp. 15-20.) To elaborate on this issue, ACOEM has a methodology in producing evidence-based guidelines. This process first involves application of a scientific method to the analyses of the body of literature by conducting a systematic review, and based on that systematic review making recommendations. The ACOEM methodology identifies and clearly defines these distinctions to make them highly transparent and reproducible. (For description of ACOEM's methodology, see response to comment submitted by Linda F. Atcherley, dated, December 22, 2006, at the top of this section.) In conducting the systematic review, for some topics, there may be robust literature and strong evidence base on which to guide recommendations. For other topics, there is an intermediate level of evidence. In a number of cases, there is not any quality evidence on which to provide evidence-based recommendations. ACOEM has clearly defined a process upon which recommendations are based on	

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			consensus, but only after the systematic review of the evidence has taken place. Consensus is not "evidence" in the scientific sense, but rather opinion based on the systematic review of the evidence. Although the specific term of "consensus" is not used is not used in the guidelines, it is built into the evaluating process because it entails agreement among experts about the ratings and strength of recommendations. A strength of the ACOEM Guidelines Practices is that this that the nature and strength of the recommendations are clearly labeled so that the reader can understand the basis of the recommendations. Moreover, In his article entitled: *Evidence Based Medicine: What it is and What it isn't,* http://www.bmj.com/cgi/content/full/312/7023/71, Sackett states: "Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research." Thus, as applicable to guideline development, the evaluating committee as indicated above, reviews the medical literature	

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			and issues recommendations which in some instances involve the agreement among the reviewing experts about the ratings and strength of recommendations. This process is what guides the consensus element in a guideline. (See also, ACOEM Practice Guidelines, APG Insights, Fall 2006, *ACOEM's Revised Evidence-Based Occupational Medicine Practice Guidelines and Methodology*, page 1.)	
Section 9792.22(c)(1)	Commenter indicates that by adopting ACOEM's revised "Strength of Evidence" scale, while apparently diffusing the fact that "consensus" (using the former terminology) could not be considered a level of evidence, the DWC will now institutionalize a proprietary methodology as yet unpublished, unrecognized nationally, and certainly not in wide use by other guideline authors. Commenter states that setting aside the merits of the methodology, with this adoption, the DWC places an undue burden on utilization review programs to compare ACOEM's current guidelines against all others that do not utilize the same evidentiary method and nomenclature.		**Disagree.** As previously stated, evidence-based medicine is a relatively new field, and continues to evolve as new standards are being adopted to systematically review the scientific evidence. ACOEM has revised its methodology to classify the evidence to comply with internationally recognized standards. ACOEM is among many organizations who are adopting similar standards in systematic review of the scientific evidence. Commenter is incorrect in stating that ACOEM's methodology is "unpublished," "unrecognized nationally," and "not in wide use by other guideline authors." ACOEM methodology is based on a system with established use worldwide. The methodology is based on a modification of the methodology used by the Scottish Intercollegiate Guideline Network (SIGN),	None.

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			http://www.sign.ac.uk/guidelines/fulltext/50/checklist2.htm. SIGN develops and disseminates national clinical guidelines containing recommendations for effective evidence-based practice, and is part of NHS Quality Improvement Scotland. Moreover, ACOEM's methodology also incorporates Cochrane Collaboration's methodology. (See, ACOEM Practice Guidelines, APG Insights, Fall 2006, *ACOEM's Revised Evidence-Based Occupational Medicine Practice Guidelines and Methodology*, at p. 2.) Therefore, DWC is not institutionalizing a proprietary methodology that is as yet unpublished as alleged by the commenter as reflected above. We stated in the notice that because ACOEM updated its methodology, and in light of the fact that we adopted ACOEM into the MTUS, Section 9792.22(c)(1) was amended to reflect ACOEM's updated methodology. We indicated that ACOEM remains the foundation for the MTUS, and the adoption of the updated methodology allows the MTUS to remain consistent with ACOEM's current methodology to evaluate evidence-based medical treatment guidelines. Just as new evidence emerges that will change treatment recommendations over	

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			time, the instrument used to evaluate the evidence will also evolve over time. We stated that this approach avoids conflict and the negation of the presumption of correctness pursuant to Labor Code section 4604.5(a). It is noted that "health care decisions are increasingly being made on research-based evidence rather than on expert opinion or clinical experience alone. Systematic review represents a rigorous method of compiling scientific evidence to answer questions regarding health care issues of treatment, diagnosis, or preventive services." See, *Evidence Report/Technology Assessment: Number 47, Systems to Rate the Strength of Scientific Evidence*, Agency for Healthcare Research and Quality (AHRQ), http://www.ahrq.gov/clinic/epcsums/strengthsum.htm. However, there are many systems available to conduct systematic review. The article cited above by AHRQ identified "40 systems that address grading the strength of a body of evidence." (At p. 5.) Moreover, in the *Cochrane Handbook for Systematic Reviews of Interventions 4.2.6*, September 2006, http://www.cochrane.org/resources/handbook/Handbook4.2.6Sep2006.pdf the Cochrane Collaboration identifies a study that compares 25 rating scales. Thus, it was important for DWC to maintain the same	

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			methodology as used by ACOEM in order to maintain consistency throughout the proposed regulations, with the goal of maintaining ACOEM as the foundation for the MTUS.	
Section 9792.22(c)(1)	Commenter states that by adopting a proprietary criterion and method, the DWC leaves treating physicians with very little chance to overcome the presumption of correctness, because no other guidelines have yet been developed using the same methods or evidentiary basis.		**Disagree.** Commenter is incorrect in stating that the proposed regulations leave treating physicians with very little chance to overcome the presumption of correctness, because no other guidelines have yet been developed using the same methods or evidentiary basis. The regulations do not require that the guidelines being used to overcome the presumption contain the same methodology for review of the evidence. The process by which the presumption may be overcome is clear in the regulations as set forth in Section 9792.22. For approach to use of the Strength of Evidence and further response on the subject, see response to comment submitted by Linda F. Atcherley, dated, December 22, 2006, at the top of this section.	None.
Section 9792.22(c)(1)	Commenter states that utilization review programs will have no basis for comparison and, thus, approval of alternate treatment plans. Commenter states that presuming that California's Schedule could set a precedent in this regard, California will force all other guidelines to adopt the same methodology in		**Disagree.** Because ACOEM's methodology is based on a system with established worldwide use, commenter is incorrect in stating that the regulations place an undue burden on utilization review programs. Utilization review will continue to use the MTUS and other	None.

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	order to be considered for future inclusion into the Schedule.		evidence-based guidelines to approve, deny or modify medical treatment.	
Section 9792.22(c)(1)	Commenter states that the California Treatment Utilization Schedule will become permanently ensconced in the ACOEM system and force specialty societies and guideline authors to adopt the ACOEM "Strength of Evidence" scale which may stifle independent analysis.		**Disagree.** DWC does not agree with Commenter's interpretation of Proposed Section 9792.22(c)(1). However, it appears from the comment that the proposed regulations are not clear as to the process to be used by the committee in making recommendations to revise, update or supplement the MTUS. DWC does not want to exclude other guidelines from being used pursuant to Proposed Section 9792.22(b). Therefore, Proposed Section 9792.23(c) has been amended to clearly reflect the Strength of Evidence is to be used to rate scientific evidence, not guidelines.	Section 9792.23(c) has been amended. The proposed section now states: (c) To evaluate evidence when making recommendations to revise, update or supplement the medical treatment utilization schedule, the members of the medical evidence evaluation advisory committee shall: (1) Apply the requirements of subdivision (b) of Section 9792.22 in reviewing medical treatment guidelines to insure that the guidelines are scientifically and evidence-based, and nationally recognized by the medical community; (2) Apply the ACOEM's strength of evidence rating methodology to the scientific evidence as set

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				forth in subdivision (c) of Section 9792.21 after identifying areas in the guidelines which do not meet the requirements set forth in subdivision (b) of Section 9792.21; (3) Apply in reviewing the scientific evidence, the ACOEM's strength of evidence rating methodology for treatments where there are no medical treatment guidelines or where a guideline is developed by the Administrative Director, as set forth in subdivision (c) of Section 9792.21.
Section 9792.22(c)(1)	Commenter states that he wants to alert the Division that this apparent solution simply trades one conflict for another and will perhaps exacerbate debates and delays over requested treatment. Commenter indicates that if unchanged, it is most certain to increase conflict in the very near term after these regulations are finalized because the ACOEM Guidelines, Second Edition, themselves were not created under the new "Strength of Evidence" scale.		**Disagree.** Commenter argues that adoption of ACOEM's revised methodology will increase conflict because the second edition was not created under the new "Strength of Evidence" methodology. We disagree. In the December 2006 Notice of Modification to Text of Proposed Regulations, at p. 20, we explained the adoption of the ACOEM methodology. Thus, the ACOEM Practice Guidelines, 2nd edition, remains a valid medical treatment guideline, and will be valid until revised by ACOEM, and	See action above on Proposed Section 9792.23(c).

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			adopted by formal rulemaking into the regulations. The purpose of the new "Strength of Evidence" is to provide additional clarity so that the guidance becomes even more transparent. DWC believes that the use of clearer methods would be expected to further reduce conflict, rather than increase it. Commenter is incorrect in implying that DWC will be using the ACOEM's Strength of Evidence to re-rate other guidelines. As indicated above, DWC does not intend to exclude other guidelines from being used pursuant to Proposed Section 9792.22(b). Proposed Section 9792.23(c) has been amended to clearly reflect the Strength of Evidence is to be used to rate scientific evidence, not guidelines.	
Section 9792.22(c)	Commenter states that evidence based medicine is not limited to intermediate and high quality studies. Commenter indicates that the MTUS should support the practice of evidence based medicine. Commenter further states that proposed rule 8 CCR 9792.22(c) sets forth a scale of strength of evidence which is valuable for ranking guidelines based on studies, but adds that the practice of evidence based medicine does not stop with studies. Commenter states that evidence based medicine means "…the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients." It means "integrating individual	Lachlan Taylor Commission on Health and Safety and Workers' Compensation December 22, 2006 Written Comment	**Disagree.** It appears that commenter is stating that Strength of Evidence will exclude "low quality studies," or that consensus will never be considered in the absence of high quality or intermediate studies. Although there may be a very limited place for low quality studies, lower quality evidence is far more likely to be overturned with better designed studies. As indicated above, in the course of guideline development, the evaluating committee reviews the medical literature and issues recommendations, which in some	None.

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	clinical expertise with the best available external clinical evidence from systematic research." (Sackett D.L et al., Brit.Med.Jnl. (1996) 312:71-80.)		instances involves the agreement among the reviewing experts about the ratings and strength of recommendations. This process is what guides the consensus element in a guideline. This is the approach that ACOEM has followed in the development of its guidelines and it is concordant with the cited philosophy of Sackett. (See also response to Steven J. Cattolica, Carlyle Brakensiek, Advocal, dated December 22, 2006, above.)	
Section 9792.22(c)(1)	Commenter goes on to say that because of the limitations of the existing body of studies, many of the ACOEM guidelines are of Level D, "Panel interpretation of information not meeting inclusion criteria for research-based evidence" (ACOEM Guidelines 2nd Ed., p. 49). Commenter states that these are still scientific and evidence based as required by Labor Code Section 4604.5(b), but they are not directly supported by studies graded A, B, or C. Commenter further states that section 9792.22(c) should specify that Tables A and B are applicable for grading the strength of evidence based on studies, but when studies applicable to the patient's clinical condition are either nonexistent or are of grade I, then treatment shall be in accordance with other evidence based, scientifically based, nationally recognized, peer-reviewed guidelines. Commenter states that the proposed regulations may have intended this already, but unless revised, the regulations are vulnerable to being misconstrued as rejecting		**Disagree.** The strength-of-evidence ratings rank bodies of evidence, not guidelines. As stated above, evidence-based medicine is anchored in high-quality evidence to ensure optimal patient benefit. Former Level D recommendations (now designated Level I), based on the analysis above, cannot be evidence-based or scientific because the evidence is absent, contradictory or unreliable. However, as indicated above, in the course of guideline development, the evaluating committee reviews the medical literature and issues recommendations, which in some instances involves the agreement among the reviewing experts about the ratings and strength of recommendations. This process is what guides the consensus element in a guideline. This is the approach that ACOEM has followed in the	None.

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	any guideline that is not based on at least an intermediate quality study.		development of its guidelines and it is concordant with the cited philosophy of Sackett. (See also response to Steven J. Cattolica, Carlyle Brakensiek, Advocal, dated December 22, 2006, above.)	
Section 9792.22(c)(1)	Commenter states that the strength of evidence scale set forth in the regulation is attributed to ACOEM's methodology. Commenter states that he has not located this specific methodology in the ACOEM Guidelines, 2nd Edition. Commenter adds that a citation to the exact source would be helpful in achieving a consistent interpretation of the regulation by allowing reference to collateral evidence of regulatory intent.		**Disagree**. As previously indicated, evidence-based medicine is a relatively new field, and continues to evolve as new standards are being adopted to systematically review the scientific evidence. ACOEM has revised its methodology to classify the evidence to comply with internationally recognized standards. ACOEM is among many organizations who are adopting similar standards in systematic review of the scientific evidence. The December 2006 Notice of Modification to Text of Proposed Regulations, provided notice to the public that the methodology adopted in the regulations is ACOEM's new methodology. Although similar to the methodology contain in the second edition, the revised ACOEM methodology is an even clearer and more transparent process that underlies the updating of the 2nd edition of the Guidelines.	None.
Section 9792.22(c)(1)	Commenter further states that the word "insufficient" in Table B, Level I, may be interpreted to mean that the material is legally insufficient to sustain the proponent's burden of proof. Commenter opines that this does not		**Disagree.** Section 9792.22(c)(1)(B), setting forth Table B—Strength of Evidence Rating, contains at the top portion of the table explanatory	None.

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	appear to be the intended meaning among guideline developers. Commenter adds that if consistent with the source of the scale, the language of Table B might be more accurately interpreted if it is amended as follows: **Insufficient Evidence:** Evidence is insufficient <u>for inclusion in Level A, B, or C,</u> or <u>contradictory evidence from studies of equally ranked quality is</u> irreconcilable. <u>"Insufficient" research-based evidence does not mean that treatment cannot be guided by other evidence based, scientifically based, nationally recognized, peer reviewed guidelines.</u> Commenter adds that this is not a complete recommendation for revisions. Commenter states that further revisions of 8 CCR 9792.22 are necessary to assure that appropriate guidelines are not ignored just because of the limitations of the existing body of studies. Commenter further states that for the areas where high quality studies have not been conducted, the MTUS must walk a fine line between stifling "the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients" and returning to "anything goes" of recent memory.		language which makes it clear that the purpose of the levels of evidence is to rate the quality of the body of scientific evidence. The proposed regulations, as set forth in that section, are clear that the term "insufficient" relates to the rating of the scientific evidence and not to the "burden of proof." Commenter proposes that the term as used in Table B be defined to mean that "research-based evidence does not mean that treatment cannot be guided by other evidence based, scientifically based, nationally recognized, peer reviewed guidelines." Commenter's suggestion is contrary to the proposed regulations, and the presumption of correctness as set forth in the statute (Lab. Code §4604.5(a)). Section 9792.22(a) provides that the MTUS is presumed to be correct on the issue of extent and scope of medical treatment addressed in the MTUS. Thus, when the MTUS addresses a medical treatment, even when the strength of evidence rating is "I", that treatment recommendation is presumed to be correct under the proposed regulations. If the physician wants to overcome the presumption, use of the Strength of Evidence Methodology could be used under Section 9792.22(c) as the physician would be proposing treatment of a condition for which the requested	

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			treatment is at variance with the MTUS. (For approach to use of the Strength of Evidence and further response on the subject, see response to comment submitted by Linda F. Atcherley, dated, December 22, 2006, at the top of this section.	
Section 9792.22(c)(1)	Commenter states that the Strength of Evidence rules are taken from ACOEM – which in his opinion – does not apply to chronic conditions. Commenter further states that utilizing the ACOEM Strength of Evidence misapplies ACOEM. Commenter indicates that the ACOEM Practice Guidelines do not apply to chronic conditions and there is no reason to assume that the Strength of Evidence have any application beyond that defined by the ACOEM Practice Guidelines themselves.	Bo Thoreen, Esq. December 22, 2006 Written Comment	**Disagree.** The comment is not specifically directed the strength of evidence methodology but at the application of the ACOEM Practice Guidelines to chronic conditions. This comment was raised during the 45-day comment period and addressed in the original responses issued after 45-day comment period. The response to this comment is contained in Response No. 11—Chronic Conditions, which is part of the 45-day comment period chart.	None.
Section 9792.22(c)(1)	Commenter states that he is concerned that the Strength of Evidence does not allow for the individual treating physician's acumen and practice experience when there are no other treatment guidelines. Commenter states that he supports the use of Strength of Evidence criteria by physician medical directors of insurance companies to determine the appropriateness of guidelines, articles or studies submitted by a treating physician or where there are conflicting studies to determine the most appropriate study. Commenter opines, however, that in instances where there are no guidelines, the proposed system would deny the clinical experience of the treating physician who is uniquely aware of the specific needs of the patient.	Joseph L. Dunn CEO/Executive Vice President California Medical Association December 22, 2006 Written Comment	**Disagree.** Commenter opines that the Strength of Evidence does not allow for the individual treating physician's acumen and practice experience when there are no other treatment guidelines. The statute requires the Administrative Director to adopt a Medical Treatment Utilization Schedule (MTUS) that is evidence-based. (Lab. Code, § 5307.27.) The statute further states that the MTUS is presumed to be correct "on the issue of extent and scope of medical treatment … and [t]the presumption may be controverted by a preponderance of the scientific evidence establishing a variance from	None.

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	Commenter states that as much as 80 percent of the care physicians provide is not addressed in treatment guidelines nor has it been reviewed through randomized clinical studies. Commenter believes that the judgment of the treating physician, within certain parameters, must prevail for treatments that are not addressed by evidence-based protocols. Commenter proposes the adoption of a new Section 9792.22(d) to address gaps in the guidelines: (d) For all other conditions or injuries not addressed by either subdivisions (a), (b), and (c) above, medical treatment and diagnostic services should be based on the views of the physicians practicing in the relevant clinical areas and any other relevant factors, including the expert opinion of the treating physician. Commenter does not believe the adoption of this language is a return to the presumption of correctness for the opinion of the treating physician. Where no other applicable guideline exists, commenter believes that the opinion of the treating physician should be honored. Payers should not be allowed to deny payment for services on the sole basis that the treatment is not addressed by evidence-based guidelines.		the guidelines…." (Lab. Code, § 4604.5(a).) Thus, a physician is required under the regulations to overcome the presumption of correctness. The process by which the presumption may be overcome is clear in the regulations as set forth in Section 9792.22. For approach to use of the Strength of Evidence and further response on the subject, see response to comment submitted by Linda F. Atcherley, dated, December 22, 2006, above.	
Section 9792.23(a)(2)	Commenter states that the function of the expert panel will be to advise the Medical Director regarding the augmentation of the medical treatment utilization schedule with additional guidelines. Commenter opines that expertise in developing and implementing	Brenda Ramirez Claims and Medical Director Michael McClain General Counsel & Vice	**Disagree**. The goal of DWC is to form a well-balanced committee. Some members of the committee will have experience in developing evidence-based treatment guidelines, while other will bring strong medical	None.

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	evidence-based treatment guidelines is an essential quality for these advisors. Commenter recommends that Section 9792.23(a)(2) be amended as follows: "The members of the medical evidence evaluation advisory committee shall be appointed by the Medical Director, or his or her designee, and shall consist of 17 members of the medical community, holding a Medical Doctor (M.D.), Doctor of Osteopathy (D.O.), who are board certified by an American Board of Medical Specialties (ABMS) or American Osteopathic Association approved specialty boards (AOA) respectively, Doctor of Chiropractic (D.C.), Physical Therapy (P.T.), Occupational Therapy (O.T.), Acupuncture (L.Ac.), Psychology (PhD.), or Doctor of Podiatric Medicine (DPM) licenses, with experience in developing evidence-based treatment guidelines, and representing the following specialty fields:"	President Alex Swedlow Executive Vice President California Workers' Compensation Institute December 22, 2006 Written Comment	expertise in the various disciplines. Moreover, DWC is in the process of developing a staff with skills necessary in evaluating medical evidence for the purposes of developing treatment guidelines and supporting the medical evidence evaluation advisory committee.	
Section 9792.23(a)(2)	Commenter references Section 9792.23(a)(2) indicating that the section limits M.D. members of that committee to those who are board certified by an American Board of Medical Specialties (ABMS). Commenter states that pursuant to a law passed in 1990 (SB 2036) to eliminate physician advertising of board certification in California based on questionable training, the Medical Board of California (MBC) established a process to review and approve certification training programs that can demonstrate "equivalence" to ABMS certification programs. Commenter indicates that to date, the MBC has approved four specialty certification programs as	Joseph L. Dunn CEO/Executive Vice President California Medical Association December 22, 2006 Written Comment	**Agree in part. Agree** with the comment that the Medical Board of California (MBC) has approved a number of specialty boards which are not part of the American Board of Medical Specialties (ABMS). Section 9792.23(a)(2) will be amended to include members of the specialty boards who are approved by the Medical Board of California (MBC).(http://www.medbd.ca.gov/alphalist.htm)	Section 9792.23(a)(2) has been amended. The Section now states: (2) The members of the medical evidence evaluation advisory committee shall be appointed by the Medical Director, or his or her designee, and shall consist of 17 members of the medical community, holding a Medical Doctor (M.D.), Doctor of Osteopathy (D.O.), who

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	equivalent to ABMS. These boards include: American Board of Facial Plastic and Reconstructive Surgery; American Board of Pain Medicine; American Board of Sleep Medicine; and The American Board of Spine Surgery. Commenter states that the MBC has a stringent and lengthy process to determine ABMS equivalence, and opines that exclusion of diplomats of boards so approved from the medical evidence evaluation advisory committee would unfairly discriminate against physicians whom the legislature intended to grant equal status with those holding an ABMS board certification. Commenter strongly urges that physicians certified by the MBC approved boards be eligible to serve on this committee, and recommends an amendment as follows: 9729.23 (2) The members of the medical evidence evaluation advisory committee shall be appointed by the Medical Director, or his or her designee, and shall consist of 17 members of the medical community, holding a Medical Doctor (M.D.), ~~Doctor of Osteopathy (D.O.)~~ who are board certified by an American Board of Medical Specialties (ABMS) or Medical Board of California (MBC) approved specialty board, or Doctor of Osteopathy (D.O) who are board certified by an American Osteopathic Association approved specialty boards (AOA) ~~respectively~~, Doctor of Chiropractic (D.C.).			are board certified by an American Board of Medical Specialties (ABMS) or American Osteopathic Association approved specialty boards (AOA) respectively, Medical Doctor (M.D.), who are board certified by a Medical Board of California (MBC) approved specialty board, Doctor of Chiropractic (D.C.), Physical Therapy (P.T.), Occupational Therapy (O.T.), Acupuncture (L.Ac.), Psychology (PhD.), or Doctor of Podiatric Medicine (DPM) licenses, and representing the following specialty fields:
Section 9792.23(a)(2)	Commenter strongly supports the Division's proposal to establish a Medical Evidence Evaluation Advisory Committee. Commenter		**Agree** that "chronic conditions" is an important topic to be addressed by the medical evidence evaluation	None.

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	further states that it is crucial that the DWC adopt additional guidelines to supplement the ACOEM guidelines, including all applicable national specialty society guidelines, as well as guidelines that address chronic conditions. Commenter states that he is very pleased that the DWC is moving quickly towards the establishment of the medical evidence evaluation advisory committee. Commenter further states that as in previous comments, he continues to receive an inordinate number of complaints about insurance carriers inappropriately denying treatment of chronic conditions based on the ACOEM Practice Guidelines. Commenter fully supports the advisory process and looks forward to the adoption of appropriate guidelines as soon as possible. Commenter urges the committee to address the treatment of "chronic" pain as its first order of business.		advisory committee. **Disagree** that all applicable national specialty society guidelines should be adopted into the MTUS. The committee will further evaluate these guidelines and determine whether they meet the requirements of the statute for purposes of adopting them into the MTUS.	
Section 9792.23	Commenter recognizes the goal of including a number of specialties on the Advisory Committee. Commenter points to two concerns about the latest proposed changes to the Advisory Committee. First, commenter opines that the creation of a 17-member committee threatens to make the Advisory Committee unwieldy and may make it difficult to achieve a consensus. Second, commenter believes that the Medical Director's discretionary appointees should not be reduced from three to two. Commenter states that there is great value in giving the Medical Director the ability to make appointments which benefit the functioning of the Advisory Committee. Commenter opines that that value should be maximized rather	Samuel Sorich President Association of California Insurance Companies December 22, 2006 Written Comment	**Disagree.** The importance of having the different disciplines set forth in Section 9792.23 involved in the evaluation of the medical evidence outweighs the need to have a small committee. The overall number of the committee members does not prevent the Medical Director from assembling smaller working groups in the various areas as they are addressed. Moreover, reduction of the discretionary members does not affect the flexibility of the Medical Director in assembling the various working groups because Section 9792.23(a)(3) allows the Medical Director to use three subject matter	None.

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	than be diminished.		experts for any given topic.	
General Comment	Commenter has no further comment regarding the proposed Medical Treatment Utilization Schedule and commends the Division for the effort put into these proposed regulations and offers ongoing support.	Jose Ruiz Claims Operations Manager State Compensation Insurance Fund (SCIF) December 22, 2006 Written Comment	**Accept**.	None.
General Comment	Commenter would like to express her appreciation for the diligence, thoroughness and speed with which the Department of Industrial Relations, Division of Workers' Compensation has addressed the issue of acupuncture in the Medical Treatment Utilization Schedule for the treatment of injured workers in the system.	Sandra Carey Carey and Associates on behalf of the Council of Acupuncture And Oriental Medicine Associations December 22, 2006 Written Comment	**Accept.**	None.
General Comment	Commenter opines that the current draft of the Medical Treatment Utilization Schedule reflects a positive effort to use the ACOEM Practice Guidelines as the primary guidelines but not as the exclusive guidelines for occupational medicine. Commenter states that a significant change from the original proposed MTUS is the latitude given to acupuncture treatment conditional on documented functional improvement. Commenter believes that it is an important achievement for the MTUS to recognize functional improvement as a criterion for medical treatment decisions.	Lachlan Taylor Commission on Health and Safety and Workers' Compensation December 22, 2006 Written Comment	**Accept.**	None.
General Comment	Commenter states that the revised regulations represent acknowledgment of commenter's and other stakeholders' earlier input to the DWC and appears to repudiate testimony attempting to establish that the ACOEM	Steven J. Cattolica Carlyle Brakensiek Advocal December 22, 2006 Written Comment	**Accept**. It is important emphasize that ACOEM remains the foundation for the MTUS, and any supplemental guidelines must be fitted to ACOEM as it provides the framework for the	None.

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	Guidelines by themselves are adequate to serve the needs of California's workers' compensation system. Commenter states that within the revised regulations, the DWC has immediately exercised its authority to include additional (or substitute) guidelines by inserting guidelines for acupuncture. Commenter adds that while the Society (organization he is representing) is not in a position to evaluate or endorse these guidelines, their inclusion is recognition by the DWC that injured workers and their treating physicians, as well as employers, must have a broader range of guidelines to call upon without resorting to evidentiary hurdles that serve to delay proper care. Commenter states that in addition, the revised regulations expand the size of the Medical Evidence Evaluation Advisory Committee. Both of these changes are positive and portend improvements to come. Commenter commends the DWC on its wisdom in finding that subsequent newsletters, clarifications and advisories published by any guideline author(s) cannot be adopted into the Schedule without a full and complete review by the Executive Medical Director's Advisory Committee. Commenter would also like to acknowledge the DWC's reconstruction of the structure of the Schedule to de-emphasize the ACOEM Guidelines individually and acknowledge that they will be one of perhaps a number of guidelines that will collectively form the basis for determining appropriate treatment to cure		MTUS appropriate for those conditions covered by ACOEM. This approach avoids conflict with the presumption of correctness pursuant to Labor Code section 4604.5(a).	

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	or relieve from the effects of industrial injuries or illnesses in California.			
General Comment	Commenter requests that the following language be added to the regulations: Payers must act expeditiously in evaluating responsibility for a claim. If the claim is accepted, worker payments must be timely in accordance with applicable statutes. Claims should be monitored for indicators of delayed recovery and, if necessary, trigger early case management to support providers in their efforts. They should play a non-adversarial role and work with the employer to define their approach.	Steven J. Cattolica Carlyle Brakensiek Advocal December 22, 2006 Written Comment	**Disagree.** The comment does not address the proposed changes made to the regulations subject to the 15-day notice.	None.
Notice	Commenter believes the proposed regulations should be subject to a 45-Day review period. Commenter opines that the proposed modifications to the text of the proposed regulations constitute wholesale changes from the version of the regulations that was the subject of public comment and a public hearing in August of 2006. Commenter cites Government Code section 11346.8, stating that this section prohibits state agencies from amending a regulation which has been changed from that which was originally made available unless the change is either non-substantial or solely grammatical in nature (which, in his opinion, the proposed modifications clearly are not), or sufficiently related to the original text that the public was adequately placed on notice that the change could result from the originally proposed regulatory action. If a sufficiently related change is made, the full text of the resulting adoption, amendment, or repeal, with the change clearly indicated, shall be made	Anthony J. DeCristoforo, Esq. Wilke, Fleury, Hoffelt, Gould & Birney, LLP on behalf of Empi, Inc. December 22, 2006 Written Comments	**Disagree**. All proposed changes in the regulations were properly noticed in conformance with the requirements of Administrative Procedure Act. Government Code section 11346.5(a)(3) requires the Notice of Proposed Rulemaking set forth an informative digest, containing in relevant part, a concise and clear summary of existing laws and regulations, if any, related directly to the proposed action and of the effect of the proposed action and a policy statement overview explaining the broad objectives of the regulation and, if appropriate, the specific objectives. Government Code Section 11346.8(c) prohibits any agency from adopting, amending, or repealing a regulation which has been changed from that which was	None.

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	available to the public for at least 15 days before the agency adopts, amends, or repeals the resulting regulation. Commenter argues that the proposed changes to the text of the proposed regulations were substantial and are not sufficiently related to the original text that the public was adequately placed on notice that the changes could result from the originally proposed regulatory action. Commenter submits various examples, which in his opinion support his argument that the proposed changes are not sufficiently related to the original proposed regulatory action in violation of Government Code section 11346.8: Commenter references Section 9792.21 (a)(2), and argues that the section substantially revises the regulation by adding the Acupuncture Medical Treatment Guidelines. Commenter argues that Section 9792.21(a)(2)(A) includes a host of new definitions related to acupuncture care. Commenter opines that the addition of this section is completely new and unrelated to the initial regulations, and introduces provisions that are so significant and unrelated to the initial draft that it fails to comply with Section 11346.8(c) of the Government Code. Commenter states that several definitions have been added to or revised in Section 9792.20. Commenter points to Section 9792.20(e), which has been added to define the phrase "functional improvement." Commenter states that he understands that the definition was		originally made available to the public pursuant to Section 11346.5, unless the change is "(1) non-substantial or solely grammatical in nature, or (2) sufficiently related to the original text that the public was adequately placed on notice that the change could result from the originally proposed regulatory action…." Commenter argues that the proposed changes to the regulations made available to the public in the Notice of Modification of Text of Proposed Regulations issued December 2006, and subject to a 15-day comment period, are not sufficiently related to original notice so as to be in violation of Government Code section 11346.5(c). DWC disagrees. The question is whether the "Notice of Proposed Rulemaking" issued in July 2006 put the public on adequate notice that the subject in question could be addressed as part of the formal rulemaking. Commenter references Section 9792.21(a)(2), and argues that the section substantially revises the regulation by adding the Acupuncture Medical Treatment Guidelines. Commenter notes that Section 9792.21(a)(2)(A) includes a host of new definitions related to acupuncture care. Commenter opines	

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	adopted from the American College of Occupational and Environmental Medicine (ACOEM). Commenter states that as it relates to the proposed regulation, it is new and unrelated to the prior version of the draft regulations. Commenter also references Section 9792.20(i) (setting forth the definition of the term "medical treatment guidelines") and argues that it has been substantially amended. Commenter further references Section 9792.20(j) (setting forth the definition of the term "peer reviewed"), arguing that it has been added to the proposed regulations. Commenter references Section 9792.21(a) and notes that it was modified to include ACOEM's Practice Guidelines into the regulations. Commenter further states the comments to Section 9792.22(b) (commenter is presumably referring to the notice) confirms that the "goal is to re-organize the regulations to reference the adoption of the MTUS, and the ACOEM Practice Guidelines, 2nd Edition, as a component of the MTUS." Commenter argues that Section 9792.22 deletes the previous methodology to rate the strength of the evidence and replaces it with entirely new criteria, found in proposed subdivision (c)(l)(A) of Section 9792.22(c), which was not part of the previous version of the regulations. Commenter concludes by opining that the changes from the previous version of the regulations are not sufficiently related to the original text that the public was adequately		that the addition of this section is completely new and unrelated to the initial notice of rulemaking, and introduces provisions that are so significant and unrelated to the initial draft of the regulations that it fails to comply with Section 11346.8(c) of the Government Code. A review of the Notice of Proposed Rulemaking (Notice) issued July 2006 reflects that the public was put on notice that the subject of acupuncture could be addressed as part of the formal rulemaking. For example, the Informative Digest/Policy Statement Overview included in the Notice, at page 2, last paragraph, indicates that "section 5307.27, requir[es] the Administrative Director … to adopt … a medical treatment utilization schedule." The Notice further states at the same paragraph that "[s]ection 5307.27 requires the medical treatment utilization schedule … ***address, at a minimum, the frequency, duration, intensity, and appropriateness of all treatment modalities commonly performed in workers' compensation cases***." (Emphasis added.) The Notice further states at page 3, paragraph 2, that "Labor Code section 4604.5 further provides that the recommended guidelines set forth	

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	placed on notice that the changes could result from the originally proposed regulatory action.		in the adopted schedule shall reflect practices that are evidence and scientifically based, nationally recognized, and peer-reviewed. ***The guidelines shall be designed to assist providers by offering an analytical framework for the evaluation and treatment of injured workers, and shall constitute care in accordance with Labor Code section 4600 for all injured workers diagnosed with industrial conditions***." (Emphasis added.) Moreover, the Notice at page 3, paragraph 4, states that "*Labor Code section 4600 provides, in pertinent part, that medical, surgical, chiropractic**, acupuncture …** that are reasonably required to cure or relieve the injured worker from the effects of his or her injury shall be provided by the employer….*" (Emphasis added.) Also, in the same paragraph it is noticed that subdivision (b) of Labor Code section 4600 which was added by Senate Bill 899, provides that … medical treatment that is reasonably required to cure or relieve the injured worker from the effects of his or her injury means treatment that is based upon the guidelines adopted by the administrative director pursuant to Labor Code section 5307.27. Because Labor Code section 4600	

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			allows for the provision of acupuncture treatment as part of the medical treatment provided to injured workers, and because the medical treatment utilization schedule must address "all treatment modalities commonly performed in workers' compensation cases" and will govern the provision of medical treatment for industrial injuries as required by the implementing statutes, the public was put on notice in July 2006 that the subject of acupuncture could be addressed as part of the formal rulemaking. Commenter further points to several definitions which have been added and/or revised in Section 9792.20. With respect to the definition of "functional improvement" set forth in Section 9792.20(e), this definition relates to the Acupuncture Medical Treatment Guidelines, and in the future may apply other guidelines as they are added to the regulations through formal rulemaking. Because the public was put on notice in July 2006 that the subject of acupuncture could be addressed as part of the formal rulemaking as discussed above, and the definition relates to the Acupuncture Medical Treatment Guidelines, the addition of this definition to the draft of the proposed regulations is not a violation of	

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			Government Code section 11346.5(c). With respect to the definition of the term "peer reviewed," it is noted that the July 2006 Notice, at page 3, paragraph 2, noticed the public that the medical treatment utilization schedule, as adopted by the Administrative Director pursuant to Labor Code section 5307.27, was required to "reflect practices that are evidence and scientifically based, nationally recognized, and ***peer-reviewed***" pursuant to Labor Code section 4604.5. (Emphasis added.) The definition was added to the draft of the regulations following the 45-day comment period following a request by the public that the definition be added to the draft of the regulations. Thus, it is clear that the "Notice of Proposed Rulemaking" issued in July 2006 put the public on adequate notice that the subject of a definition of the term "peer reviewed" could be added to the proposed regulations as part of the rulemaking. Commenter also references Section 9792.20(i) ("medical treatment guidelines") and argues that it has been substantially amended. Again, the July 2006 Notice put the public on notice that the proposed regulations contained a proposed definition for the term "medical treatment guidelines" (formerly Section 9792.20(i)." Commenter cannot argue that the	

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			definition of "medical treatment guidelines" as amended is not sufficiently related to the original text that the public was not adequately placed on notice that the change could result from the originally proposed regulatory action. Commenter further references Section 9792.21(a), and notes that it was modified to include ACOEM's Practice Guidelines into the regulations. Commenter further states the comments to Section 9792.22(b) (commenter is presumably referring to the December 2006 Notice of Modification of Text of Proposed Regulations) confirms that the "goal is to re-organize the regulations to reference the adoption of the MTUS, and the ACOEM Practice Guidelines, 2nd Edition, as a component of the MTUS." It is unclear why commenter believes that the changes in Sections 9792.21(a) and 9792.22(b) are not sufficiently related to the original text that the public was not adequately placed on notice that the change could result from the originally proposed regulatory action. The July 2006 Notice was clear that the proposed regulations were noticing the adoption of the medical treatment utilization schedule. This is noticed in the Notice at page 2, Informative Digest/Policy Statement Overview, at	

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			pages 2-3, and at page 5, Section 2- setting forth Section 9792.21, entitled "Medical Treatment Utilization Schedule." The section clearly indicates that Section 9792.21 "sets forth the medical treatment utilization schedule," and Section 9792.21(a) incorporates the ACOEM Practice Guidelines "into the medical treatment utilization schedule." Commenter is correct that the December 2006 Notice of Modification to Text of Proposed Regulations explained the changes in Sections 9792.21(a)(1) and 9792.22(b), wherein the goal was to re-organize the regulations to reference the adoption of the MTUS, and to reflect the ACOEM Practice Guidelines, 2nd Edition as a component of the MTUS. (At p. 13.) Thus, the changes in Sections 9792.21(a) and 9792.22(b) are sufficiently related to the original text of the July 2006 Notice of Proposed Rulemaking and the proposed draft of the regulations that the public was adequately placed on notice that the change could result from the originally proposed regulatory action, and commenter's objections to these changes are without merit. Lastly, commenter argues that Section 9792.22 deletes the previous methodology to rate the strength of	

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			the evidence and replaces it with entirely new criteria, found in proposed subdivision (c)(l)(A) of Section 9792.22(c), which was not part of the previous version of the regulations. The July 2006 Notice, at page 5, Section 3, set forth Section 9792.22—which, in pertinent part, set forth a hierarchy of scientific based evidence. The last paragraph of page 5 of the July 2006 Notice referencing Section 9792.22(c)(1) explained that the proposed regulations contained a hierarchy of evidence and explained under what circumstances the hierarchy of evidence applied. The hierarchy of evidence was based on ACOEM's hierarchy of evidence at the time of the notice. The December 2006 Notice of Modification of Proposed Regulations set forth at page 15, a new hierarchy of evidence now named "strength of evidence." This change resulted from ACOEM amending its strength of evidence (formerly named hierarchy of evidence), and is directly related to the original text of the July 2006 Notice and text of proposed regulations setting forth a hierarchy of evidence. Thus, the changes in Section 9792.22(c) are sufficiently related to the original text of the July 2006 Notice of Proposed Rulemaking and the proposed draft of the regulations that the public was	

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			adequately placed on notice that the change could result from the originally proposed regulatory action, and commenter's objections to these changes are without merit.	
Notice	Commenter expresses concern at the lack of adequate notice provided for comment on these regulatory changes. Commenter states that pursuant to Government Code § 11346.8(c), a 15-day notice period is authorized only with respect to amendments that are "sufficiently related to the original text that the public was adequately placed on notice that the change could result from the originally proposed regulatory action." Commenter opines that the amendments included in this version of the proposed regulations far exceed anything that could have been foreseen by the initial regulatory proposal. Commenter further states that these amendments will have a profound impact on the welfare of injured workers in California, and adequate notice and comment is crucial to ensure the health of these workers are not unnecessarily jeopardized. Commenter cites Labor Code § 3202 (which provides that workers' compensation provisions must be liberally construed "with the purpose of extending their benefits for the protection of persons injured in the course of their employment").	Joseph L. Dunn CEO/Executive Vice President California Medical Association December 22, 2006 Written Comment	**Disagree**. Commenter does not reference the specific changes in the proposed regulations which he believes are not "sufficiently related to the original text that the public was adequately placed on notice that the change could result from he originally proposed regulatory action." DWC believes that all changes in the proposed regulations were properly noticed in conformance with the requirements of Government Code sections 11346.5 and 11346.8. Further, see response to comment submitted by Anthony J. DeCristoforo, Esq., dated December 22, 2006, above.	None.